PRECLINICAL AND OPEN CLINICAL TRAIL OF GANDHI MATHIRAI (INTERNAL MEDICINE) AND SAGALA RANANGALUKUM KALIMBU (EXTERNAL MEDICINE) IN THE TREATMENT OF MADHUMEGA VIRANAM (DIABETIC ULCER)

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled “Preclinical and open clinical trial of *Gandhi mathirai* (Internal) and *Sagalaranagalukum kalimbu* (External) in the treatment of *Madhumega viranam*(DIABETIC ULCER) is a bonafide and genuine research work carried out by me under the guidance of**Dr.V.Mahalakshmi,M.D(s),** Lecturer**,** Department of **SirappuMaruthuvam**, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date:

Signature of the Candidate

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12.	**ANNEXTURE** **CERTIFICATES** **CASE SHEET PROFORMA**	
13.	**BILBILOGRAPHY**	

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INTRODUCTION

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INTRODUCTION

Siddha system of medicine is most ancient spiritually enriched one. Traditionally it is taught that the siddhars laid the foundation for this siddha system of medicine. Siddhar,had a wide knowledge about all fields of medicine and excelled in surgical practice. Stone inscription in various parts of south India shows the evidence of surgical treatments used in olden days. In the ancient literature *Pathitru Paththu*of cheraa king he its 5thpart includes the versus as follows;

The scar on his chest …scars of glory…
The scar made by long sutures
Wrought by needle of silver glow
Dug and drawn like the fish of cool water
Down and up as it goes….

These sequence talks about the instruments used, the type of treatment accorded and the efficacy of the surgical treatment in olden days.

As per siddha literature disease are classified into 4448 types, According to sage *Yugi Vaithiya Sinthamani ''Neer Izhivu Noi''*classified into 20 types called *Thithippu Neer* and it may be correlated with diabetes mellitus in modern aspect. Diabetic complications are retinopathy, macular edema, cataracts, glaucoma, neuropathy and ulceration of feet. Saint *Yugimuni* has described the complication of *Madhumegam* as *Avathaigal*, which are ten in numbers. Ulceration of feet may be correlated with *Avathaigal* number eight. In the text, *Agathiyar Rana Vaithiyam; Viranam* is classified into two types *Thutta Viranam, Athutta Viranam*. Mathumega viranam comes under the classification of Thutta Viranam.

"ஏனான எட்டாவ தவத்தை தானே
எழுகிரந்தி பிளவை யுந்தான் மிகவுண்டாகும்."

- யூகிவைத்திய சிந்தாமணி

In siddha system of medicine, various types of wound management are performed since olden days. There are *Thylam* (Medicated oil), *Neer* (Medicated aqueous extract), *Podi* (Medicated powders), *Pugai* (Wound Fumigation), Seelai (Medicated plaster),

Attaividal (Leech therapy), kudineer (Medicated decoction), varti (Wound plug), kalkam (Medicinal paste),Vennai (Medicated ghee).These forms are utilized in enabling a wound to attain healthy and healing stage from infective state.

"நெய்க்கிழி வைக்கப்பட்டார்,நெய்ப்பத்தல் கிடத்தப்பட்டார்
புக்குழிஎஃகம்ன்நாடி இரும்பினால் போழப்பட்டார்"
"முதுமரப்பொந்து போல முழுமெய்யும் புண்களுற்றார்க்கு
இது மருந்தென்ன நல்லார் இழுதுசேர் கவளம்வைத்து"

சிந்தாமணி-காந்தருவதத்தை இலம்பகம் – 324

Diabetes is one of the most important and common metabolic disorder that impedes the normal steps of the wound healing process. It is classified as either neuropathic, neuroischemic or ischemic. High blood glucose level for long duration damage blood vessels leads to reduce blood flow to the foot. This poor blood circulation contributed to the formation of ulcer and impairs wound healing; loss of sensations develops pressure spots and accidentally injures the skin, soft tissue, bones and damage the nerve. Diabetic ulcer affects about 12% of diabetes population. Prevalence rate between0.08 to13%.It was estimate that in 2012 approximately 37 million people have diabetes and in every 20 sec a lower limb lost due to diabetes globally. In India, it is estimated that approximately 40,000 legs are being amputated every year, of which 75% are neuropathic with secondary infection. Certain factors, such as, barefoot walking, illiteracy, low socioeconomic status, ignorance about diabetic foot care these are all high prevalence for diabetic ulcer.

This divine system of medicine is a treasure of numerous herbal, mineral, metals and herbomineral medicinal preparation such has *Chooranam, Parpam, Chendooram* etc. There are 32 forms of internal and external medicines. Author chosen *Gandhi mathirai* (Internal) and *Sagala ranagalukum kalimbu* (External) in the treatment of *Madhumega viranam.*

Ingredients of *Gandhi mathirai* are *Gandhagam (sulphur), Kaatupagal (Momorandica dioica), Karunei kizhangu (Typhonium trilobatum), Kadukkai (Terminalia chebula)*and *Sagala ranagalukum kalimbu, Lingam (Cinnabar), Mirutharsingi (Leadore), Rasakarpooram (Calomel), Vellai kungilium (Vateria indica), Kadukkai (Terminali chebula),Masikkai (Quercus infectorius), Thandrikkai (Terminalia bellerica), Kaichukkatti (catechu).*

kalimbu is effective in treating chronic non healing ulcers. The astringent action of *sagalaranagalukum kalimbu* arrest bleeding in deep ulcers and heals the wound. These ingredients are having wound healing activity and anti-diabetic activity hence the author preferred this medicinal preparation for diabetic ulcer.

AIM AND OBJECTIVES

AIM:

- Preclinical and Open Clinical Trial of *Gandhi Mathirai* (Internal Medicine) and *Sagala ranangalukum kalimbu* (External Medicine) in the treatment *of Madhumega viranam* (Diabetic Ulcer)

PRIMARY OBJECTIVE:

- To evaluate the therapeutic efficacy of"***Gandhi Mathirai"***(Internal) and "***Sagala Ranangalukum Kalimbu***"(External) in the treatment of *Madhumega Viranam(Diabetic Ulcer).*

SECONDARY OBJECTIVES:

- To study the Siddha basic principles such as Envagai thaervu, Neerkkuri, Neikkuri.
- To evaluate the safety of the trial drugs by performing toxicological studies, acute and chronic in animal models.
- Biochemical analysis of drug**.**

LITERATURE REVIEW OF *MADHUMEGA VIRANAM* IN SIDDHA ASPECT

Definition

An ulcer is a breach of the continuity of the skin, epithelium or mucous membrane caused by sloughing out of inflamed necrotic tissue.

Aetiology

"கோதையர் கலவி போதைகொழுத்தமீ னிறைச்சி போதைப்
பாதுவாய் நெய்யும் பாலும் பரிவுடனுண்பீ ராகில்
சோதபாண் டுருவ மிக்க சுக்கிலம் பிரமேகம்ந்தான்
ஓதுநீ ரிழிவு சேர வுண்டென வரிந்து கொள்ளே."

- (அகத்தியர்-1200)

"இருமியேவாதமும்பித்தமுங்கூடில்
மருவுசல மேகம் வாருதி போலகும்
உருவம்வே ராகும் உண்டவுடல் காந்திடும்
உருகவே ஊனோடு உ றிஞ்சி இனிக்கும்
பார்திடும் மூன்றும் பதிந்து மெலிந்து நிற்கில்
தேர்ந்திடும் மேகம் உள்ளே
தோன்றிடும் பொருந்தி மெய்யில்."

"ஏனான எட்டாவ தவத்தை தானே
எழுகிரந்தி **பிளவை** யுந்தான் மிகவுண்டாகும்."

- யூகிவைத்திய சிந்தாமணி

Causes of ulcer in various text,

In the text of ***Siddhar Aruvai Maruthuvam Viranam***, mainly occur due to trauma, burns, bite and derangement of humours.

According to the text of *Agathiyar Rana Vaithiyam* causes of ulcer are,

- Derrangement of three humours
- Trauma

According to the text of *T.V. Sambasivam Pillai* dictionary,

- Idiopathic
- Traumatic

Common site of the ulcer

According to the text of *Agathiyar Rana Vaithiyam*,

- Thol (Skin)
- Iraichi (Muscle)
- Perunarambu (Arteries and veins)
- Sirunarambu (Capillaries)
- Keel (Joints)
- Elumbu (Bones)
- Vayiru (Abdomen)
- Marma nilayangal (Genital organs)

According to the text of *Virana Karappan Sigitchai*

- Thol (Skin)
- Virai (Blood vessels)
- Maamisam (Muscle)
- Thassai naar (Tendon)
- Sandhigam (Joints)
- Elumbu (Bone)
- Kudalgal (GIT)
- Marma nilayangal(Sirasu-head,irudhayam-heart,siruneerpai-urinary bladder)

Sathiya ranam

Healthy adults easily recovered from this condition.

Kadina sathiya ranam

- Thodai (thigh)
- Yoni (vagina)
- Aan kuri(Penis)
- Uthadu (Lips)
- Muthugu (Trunk)
- Thadai (Mandible)
- Kan(Eyes)
- Pal (Teeth)
- Naaku (Tongue)
- Perunarambu (Major arteries and veins)

- Sirunarambu (Capillaries)
- Vayiru (Abdomen)
- Sevi (Ear)
- Vila (Rib cage)
- Akkul (Axilla)
- Maarbu (Mammillary region)

CLASSIFICATIONOF ULCER

பிறந்திடும் ரோகந் தன்னில் பேதமேப் பிரித்துப் பேச
அறிந்து மேகங்கள் தன்னுல் **அருரண** மிருபதாகும்
பொருந்திய வாதந் தன்னுல் **பொருரண** மொன்பதாகும்
மருந்தியல் பித்தம் பத்து வளர்சிலேற்பனம் பண்ணிரெண்டே.

- **அகத்தியர் ரணநூல்**

According to the text of ***Agathiyar Rananool*** ulcer can be classified into three types there are Vatham – 9, Pitham – 10, Kabam - 12

Major classification of ulcer in the text of ***Agathiyar Rana Vaithiyam***,

Vathapithakabam - *Nija Viranam*
Thondham - *Aaganthu Viranam*
Sutha viaranam

Depending upon the symptoms ulcer is classified into two types there are

Thutta viranam- 4
Athutta viranam - 45 - *Agathiyar Rana Vaithiyam*

In the basis of derangement of three biological humors ulcer can be classified into 16 types,

- Vali pun
- Pitha pun
- Iyya pun
- Vali pitha pun
- Vali iyya pun
- Pitha iyya pun
- Mukkutra pun

- Kuruthi pun
- Kuruthi thee pun
- Kuruthi vali pun
- Kuruthi iyya pun
- Kuruthi vali pitha pun
- Kuruthi vali iyya pun
- Kuruthi pitha iyya pun
- Kuruthi mukutra pun
- velutha kuruthi pun

-Siddhar Aruvai Maruthuvam

Classification of ulcer in the text of T.V.*Sambasivam Pillai* dictionary,

- Neruppu pun (Burns)
- Mega pun (Venereal ulcer)
- Vellai pun (Gonorrheal ulcer)
- Aaraa pun (Chronic non healing ulcer)
- Kiranthi pun (Syphilitic secondary rashes)
- Ottu pun (Contagious sore)
- Kuzhi pun (Deep sore or perforating ulcer)
- Raasa pun (Diabetic carbuncle)
- Karappan pun (Eczema)
- Parangi pun (Syphilitic primary sore)
- Vettu pun (Incised wound)
- Kaaya pun (Traumatic ulcer)
- Azhi pun (Sloughing sore)
- Korukku pun (Chancre)
- Veditha pun (Fissure ulcer)
- Azhar pun (Inflammed ulcer)
- Rasavekkadu pun (Ulcer caused by mercurial poisoning)
- Putru pun (Fungus ulcer)
- Vayitru pun (Gastric ulcer)
- Thulai pun, Purai pun (sinus)
- Ari pun (Rodent ulcer eating away the tissues)

In the text of siddha system of diseases ulcer classified into,

- Saruma pun (dermatitis)
- Adhirvu pun (dermatitis traumatica)
- Thee pun (dermatis calorica)
- Kulirchi pun (chill blains or frost bite)
- Azhu pun (dermatitis gangrenosa)
- Nanju pun (dermatitis medicamentosa)
- Veppu noi pun (pruritis and urticaria)
- Kiranthi (venereal ulcer)
- Korukku pun (chancroid)

SYMPTOMS OF ULCER:

According to the text of *Siddhar Aruvai Maruthuvam,* classification of ulcer based on the derangement of three biological humors,

S. NO	TYPE	COLOUR	PAIN/ BURNING SENSATION	DISCHARGE / SMELL	ONSET
1.	Vali pun	black, red or white in color	pricking pain	purulent discharge	-
2.	Azhal pun	yellow, red, dark red or pale red in color	pain and burning Sensation and redness present in ulcer	Clear discharge	Acute
3.	Iyya pun	Pale in colour	Itching and pricking pain	Sticky discharge	Gradual
4.	Vali pitham	Redness	Pricking pain	Clear and scanty discharge,foul smell.	-
5.	Vali iyyam	Pale in colour	Pricking pain and itching present	Sticky discharge	-
6.	Pitha iyyam	Pale in colour	Burning sensation and pain present,mild heat present around the ulceration	Sticky discharge	-
7.	Mukkutram	Which present in the mixture of vaatham,pitham,kabam			
8.	Kuruthi pun	Red or coral in colour	Very Painful	Bloody discharge and symptoms are similar to dhutta viranam	-
9.	Kuruthi vali pun	Red in colour	Rough,severe pain is found	Bloody stained discharge	-

10.	Kuruthi pitha pun	Red and yellow in colour	Mild pain present	Clear discharge and bloody stained	-
11.	Kuruthi iyya pun	Red in colour	Swelling and itching present	Bloody discharge	-
12.	Kuruthi vali pitha pun	Mixture of features of both kuruthi vali pun and kuruthi pitha pun			
13.	Kuruthi vali iyya pun	Mixture of features of both kuruthi vali kuruthi iyya pun			
14.	Kuruthi pitha iyya pun	Mixture of features of both kuruthi pitha and kuruthi iyya pun			
15.	Kuruthi Mukkutra pun	Mixture of the features of kuruthi vali,pitham,iyyam			
16.	Velutha kuruthi pun	Ulcer is pale red in colour, centrally elevated,and shiny without any discharge.			

According to *Agathiyar Rana Vaidhyam*,

Dhutta viranam **:** ***4***

Athutta viranam **:** ***15***

Dhutta viranam Chronic non healing ulcer

Athutta viranam **:** Healing ulcer purulent discharge present in the ulceration**.**

Sutha ratha viranam **:** Papular lesion present around the ulceration with raised floor.

Dhutta viranam sub types:

1. **Dhutta vaatha viranam –** ulcer black and white in colour.it may be deep seated and sometimes penetrating the bone, pricking pain with purulent discharge present around the ulceration.

2. **Dhutta pitha viranam –** ulcer is reddish white or yellow in colour, sudden onset,clear discharge present in ulceration,burning sensation and pain preset around the ulcer.

3. **Dhutta silaethuma viranam –** raised edge, itching and pain present in the ulceration discharge sticky in nature.

4. **Rathavaatha dhutta viranam –** bright red in colour or coral like colour,blood stained discharge present in ulceration.

According to *Anubava Vaithya Deva Ragasiyam*,

Sathiyo viranam

- **Krishta viranam** - It is a chronic non–healing ulcer occurs due to accidentally injure with thorn and horn.
- **Avakartha viranam** - It is perforated with deep seated ulcer
- **Vichinna viranm** - cut wound
- **Piravilambi viranam** - Ulceration is cut wound and it may deep seated with penetrating to the wound.
- **Nibaathika viranam** - Compared with gangrene stage, in this type ulceration involve with bone and it can be surrounded by necrotizing tissue.
- **Vitha viranam** - Traumatic ulcer
- **Pinna viranam** - Mainly due to injure with sword, sharpie instruments.
- **Vithalitha viranam** - Bleeding ulcer, it may lead to arthralgia and spreading nature.

According to *Viranakarappan Roga Sigitchai*:

Nija viranam

Simple ulcer, it's occurring due to derangement of three humours.

Aaganthu viranam

This type occurs mainly due to trauma.

Dhutta viranam:

- Margin of the ulcer it may be closed or open; it may be extensively soft or hard in nature.
- Base of the ulcer is raised or deep seated
- Surrounding area may be inflamed or not
- Color of the ulcer is red, white, and black.
- Purulent discharge
- Ulcer is very painful, itching, swelling present around the ulcer.

Sutha viranam:

- Ulcer may be pale in color, surrounding area hyper pigmented with purulent discharge and inflamed.

Curable and incurable conditions of ulcer:

புண்ணும்வெளுத்து நீர்மிகுந்து போதக்குத்துவலி மிகுந்தால்
உண்மைப்படவேன் செங்கலங்கல் கொள்ளாதிருக்கிலான் செய்யும்
திண்மைப்படவே செங்கலங்கல் யிரத்தமாகிற் தீராது
நன்னிக்கிழாய்ச் சீழ்விழுந்து பின்னைநனைக்குஞ் செம்புண்ணே

- **விரணகரப்பான் சிகிச்சை**

According to the *Viranakarappan Sigitchai,*

Curable

- Healthy adults
- If the shape of the ulcer is oval or circular are easily curable
- Maintain proper hygienic improves the wound healing process.
- If the ulcer develops in male genitalia, lips, oral cavity it can be easily treatable.

Incurable

- Ulceration with extensive destruction or tissue necrosis or surgical removal of blood vessels may interrupt the healing process.
- Ulceration involves in tendon, muscle, bone delays wound healing process.
- Improper medication and dressing
- Toxic bite induced ulcer
- Alcohol

Siddhar Aruvai Maruthuvam

Curable

- Age of affected person
- If the shape of the ulcer is oval, triangle, rectangles are easily curable

Incurable

- Improper medication may delay the wound healing process.
- Chronic ulcer with secondary infections such as TB, leprosy which may delays the wound healing process.
- If ulceration develops in eyes, nostrils, abdomen, chest and joints may interrupts the wound healing process.
- Ulcer with increased purulent discharge, raised floor, extensive and localized gangrene, osteomyelitis, deep ulceration with bone and tendon, joints this condition are difficult to treat.
- If the ulcer occur in vertex, fingertip, vital points, deep seated wound which penetrate the bone and bone marrow are difficult to treat.

WOUND CARE IN SIDDHA ASPECT:

According to text of *Viranakarappan Roga Sigitchai- Banthanam* (Bandaging);

There are 15 types of bandaging methods are described

Kosabandhanam
Svasthiga banthanam
Muthhtoli banthananam
Seena banthanam
Thaama banthanam
Anuvellitha banthanam
Katvaa banthanam
Vibantha banthanam
Sthagitha banthanam
Vithaana banthanam
Uthsanga banthanam
Koobana banthanam
Yamaga banthanam
Mandala banthanam
Panchanga banthanam

Indication

- Traumatic ulcer
- Cuts
- Ulcer with purulent discharge conditions
- Bleeding ulcer

Contra -Indications:

- Hansen's ulcer
- Burns
- Diabetic ulcer
- Herpes zoster

KATTU-(COMPRESS OR BANDAGE)

kattu is an application of covering of a specially prepared topical medicine made up of crude plants, birds, fermented water or inorganic substance on the affected area is known as kattu. This procedure is usually done for three times, at an interval of 3-7 days.

Indication

- Abscess
- Carbuncles
- Supperative and Non supperative ulcer

Contraindication

- Deep ulcers with foreign bodies
- Cellulitis

PATRU-(SEMISOLID POULTICE)

The raw materials are either ground or juices of leaf, bark, root are heated or not heated and applied or paste on the affected area. It is a soft moist, usually made up of herbals which is applied in the skin diseases, abscess as emollient, anti-microbial and anti-allergic. This method is commonly used to treat wound and abscess where the built up pus needs to draw out.

Indication

- Abscess
- Carbuncle
- Initial stage of ulcer

Contraindication

- Deep ulcers
- Gas gangrene
- Cellulitis

POOCHU-(LIQUID POULTICE)

This is the external application of leaf juice in affected area, normally the medicine in the liquid form either in oil base or water base is spread evenly on affected area. Its develops a thin layer spread on the affected areas due to its liquid nature.it is also called as ellai poochu ,kashaya poochu, ennai poochu etc. This procedure involves the purification, lubrication, moisturization, local healing, and analgesic.

Indication

- Wounds
- Sinus ulcers
- Fissure foot
- Ulcer with hyperpigmentation

Contraindication

- Cellulitis
- Traumatic ulcer

KALIMBU-(OINTMENT APPLICATION)

This is a form of medicine used externally in the form of ointment. In this certain mineral compounds astringent material like *Terminalia chebula* are powdered and grounded with butter and applied over wounds and ulcer.

Indication

- Chronic skin ulcers
- Fissure
- Abscess

Contraindication

- Direct contact with eyes

SEELAI-(PLASTER APPLICATION)

This type of external medicine is in the form of medicated plasters. Plasters are prepared by grinding herbal or mineral material in water or herbal juices. A piece of cloth is soaked in this and externally applied over wounds. Medicated gauze is used for the application of a wound in order to promote healing and prevents further harm. This method is absorbed the exudates and debris from a wound and promotes the healing by fastening the epithelial formation.

Indication

- Chronic non healing ulcers
- Fissures
- Abscess
- Fistula

Contraindication

- Malignant growth using caustic plasters

NEER-(MEDICATED LIQUIDS)

Neer is defined as the method of soaking the drugs into the water or making a decoction or dissolving the dry powder into the water and the filtered solution is applied over the affected area to treat or wash.

E.g. *Padigara neer, Veera neer,* are used in washing wounds.

Indication

- Acute and chronic ulcers
- Apthous ulcer
- Eczema
- Fissure
- Fistula

Contraindication

- Perforated ulcers
- Necrosis

VARTHI- (MEDICATED WICK)

This type of external medicine is in the form of medicated wicks. Caustic substances are ground well with herbal juices or decoctions; a piece of cloth soaked in this and a wick is prepared. These wicks are applied or inserted into granulomatous tracks in fistula, sinus, and non-healing ulcers.

Indication

- Abscess
- Carbuncle
- Chronic and perforated ulcer
- Fistula
- Sinus
- Infected ulcer with tissue growth

Contraindication

- Septicemia

PASAI-(EMBROCATION APPLICATION)

Pasai is defined as the mixture of medicated powders with specific oil melted honey bee wax.its otherwise called as *lepam or mezhugu*.These are semi-solid lipid or resin or gum based application. Usually fats are used as bases of vegetable oiland bee wax. They protect and stay in the skin as emollient for a long time.

Indication

- Abscess
- Ulcer

Contraindication

- Direct eye contact

PODI-(MEDICATED DUST OR POWDER APPLICATION)

Podi is defined as the finely powdered raw drugs used to sprinkle affected areas.it is dusted over the chronic weeping or purulent wound.it has two types one is dry powder for sprinkling,dry powder mixed with oil or liquids.

Indication

- Wound
- Non healing ulcer
- Eczema

Contraindication

- Eyes and nasal application
- Nasal inhalation

SUTTIGAI-(CAUTERIZATION)

This is destruction of tissues with a cautery. They are traditionally used to stop heavy bleeding; this would cause tissues and blood to heat rapidly to extreme temperature causing coagulation of the blood this control bleeding. According to the physical nature and administration, it is classified into five types, *Mann suttigai*(application of mud or stone),*Mara suttigai*(application of hot plantparts),*kaal suttigal*(application of hot air),*kaanthi suttigai*(application of sun rays), *Uloga suttigai*(application of hot metals).

Indication

- Wounds especially bleeding ulcers
- Non healing ulcer
- Infected ulcer with tissue growth
- Carbuncle
- Deep ulcers
- Fistula

Contraindication

- Burn shock
- Dehydration
- Keloid
- Sun stroke

PUGAI-(FUMIGATION)

Fumigation is method of applications in which the medicated fume is generated by burning the drugs directly or putting the drugs into the fire. It commonly expose on the site or exposing fume on septic wound by burning a medicated wick.

Indication

- Chronic non healing ulcer
- Fistula

Contraindication

- Status asthmaticus
- Suffocation
- Immediately after eye operation

URINJAL–(PIPE ASPIRATION)

Urinjal is a suction process using a special probe or aspiration process using a needle to exudates the waste fluid or unwanted fluids from the body parts.it plays an important role during surgical process to aspirate and drain the accumulate fluids such as pus, blood.

Indication

- Abscess
- Carbuncle
- To remove unwanted material from deep-seated ulcer

Contraindication

- Blood coagulation
- Coronary artery disease

KURUTHI VANGAL–(INSTRUMENTAL BLOOD LETTING)

Kuruthi vangal is an external method of application of sharp instruments to leak or remove the blood from the abscess, cyst, keloid or the area where the accumulated blood are seen. In this type of treatment a minor incision is made on the blood vessel and the excess of blood is let out. Types are one is incision to let normal blood in bloodletting therapy and another one is incision to let purulent or impure blood from the affected area.

Indication

- Transudate and exudate
- Abscess
- Cyst

Contraindication

- Convulsion
- Pregnancy
- Tuberculosis

KEERAL - (INCISION AND DRAINAGE)

Keeral is an incision to remove blood or pus or mucus from the abscess, cyst.Keeral or incision helps to remove the accumulated pus,blood by using the sharp probe. The sharp probe used for this called kombi, it’s about 25 cm length, and in brow shape.

Indication

- Abscess
- Carbuncle
- Sebaceous cyst

Contraindication

- Blood coagulation disorder
- Tumor

KARAM-(CHEMICAL CAUTERIZATION)

Karam is application of caustic chemicals on the affected area to excise or remove the unwanted tissue or slough and debris. This procedure used to remove the slough, debris and unwanted growth and improves the healing process of the non-healing ulcer. It is the method of the application of medicated caustic drugs over the area of the chronic ulcers.

Indication

- Abscess
- Chronic non healing ulcer
- Cancerous foul smell growth
- Fistula

Contraindication

- Pain shock
- Localized gangrene
- Deep seated ulcer

ATTAI VIDAL-(LEECH THERAPY)

Attai vidal is an external method of application of medicinal leech to remove impure blood from the affected site. According to *Therayar tharu*, leech therapy is classified into 4 types. In wound management leech therapy can be used to treat chronic venous ulcer, non-healing ulcers. No of leech is depends upon the e site and nature of diseases. Leech saliva contains the presence of a variety of bioactive peptides,proteins involving anti-thrombin and anti-platelet, factor Xa inhibitors and others, these active molecules used to treat many chronic illness.

Indication

- Varicose ulcer
- Varicose eczema
- Keloid

Contraindication

- Blood coagulation disorder
- Coronary heart disease

SIDDHA PATHOLOGY

According to the siddha aspect, a disease occurs mainly due to the derangement of three biological humours namely *Vatham*, *Pitham*, *Kabam.* In diabetes, ulceration mainly occurs due deranged *kabam* and physical constituents of the body.

PINIYARI MURAIMAI (DIAGNOSTIC METHODS):

Piniyarimuraimai is the method of diagnosing disease. It is based on the following principles:

Poriyal aridhal

Pulanal aridhal

Vinaathal

Poriyal aridhal and *Pulanal aridhal* means examining the patients **'***Pori'* and '*Pulan'* with that of physicians, *ori'* and '*Pulan'*.

Imporigal

- *Mei* (Skin)
- *Vai* (Tonge)
- *Kan* (Eyes)
- *Mooku* (Nose)
- *Sevi* (Ear)

Impulan:

- *Osai* (Sound)
- *Ooru* (Sensation)
- *Oli* (Vision)
- *Suvai* (Taste)
- *Naatram* (Smell)

Vinathal:

"*Vinaathal'* is a method of enquiring about the details of the patient's problem from his own words or from his parents or attenders who are taking care of the patient, when the patient is not able to speak (or) if the patient is a child.

***Envagai thervugal* (Eight tools of examination)**

தரணியிலுள்ள வியாதிதன்னை யட்டாங் கத்தால்
தானறிய வேண்டுவது யேதோ வென்னில்
திரணியதோர் நாடிகண்கள் சத்தத் தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
இரணமல மூத்திரமா மிவைக ளெட்டும்
இதம்படவே தான்பார்த்துக் குறிப்புங் கண்டு
பரணருளால் பெரியோர்கள் பாதம் போற்றிப்
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே - **குணவாகடநாடி**

Sparism - To examine the sensation, temperature and nature of the skin

Naa - To examine the Colour of saliva, sputum and nature of speech.

Niram - To examine the Variation in pigmentation of skin.

Mozhi

- *Vaatham* (Normal pitch)
- *Pitham* (High pitch)
- *Kabam* (Low pitched)
- *Thontham* (Mixed all the above)

Vizhi

- *Vaatham* (Black in colour, increased lacrimation))
- *Pitham* (Yellow or red in colour)
- *Kabam* (White in colour)

Malam

- *Vaatham* (Stools are black in colour and constipated)
- *Pitham* (Yellowish white in colour)
- *Kabam* (White in colour)
- *Thontham* (Mixed colour)

Moothiram

Collection of urine for the determination of *Neerkkuri* and *Neikkuri*, is an important diagnostic method

NAADI NADAI

In *viranam*,

வாதகப நாடி

"இருக்குமந்த வாதத்தில் சீதஞ் சேர்ந்தால்
இளைப்பிருமல் விடசந்நி தோடம் வீச்சு
மருக்கின்ற குளிர்காய்ச்சல் **விரண** தோடம்
வாந்தி எடுத்திடுமுளைவு மயக்கஞ் சோர்வு
ஒருக்கின்ற மலபந்தம் பொருமல் வீக்கம்
உள்வீச்சு சூலையோடு பாண்டு ரோகம்
தருக்கின்ற தனுர்வாதம் பக்கவாதம்
சார்ந்துவெகு பிணிபலவுந் தழைக்கும் பாரே." - **சதக நாடி**

கபநாடி

"தானமுள்ள சேத்துமந்தா னிளகில் வெப்பு
சயமிருமல் ஈளைமந் தார காசம்
ஈனமுருஞ் சந்நிவிட தோடம் விக்கல்
இருத்துரோகங் கரப்பான் **விரண** தோடம்
மானனையீர் சூலைதிரள் வியாதி வீக்கம்
வருஞ்சக்தி சுவாசம்நெஞ் சடைப்பு,துக்கம்
ஏனமுறுங் காமாலை பாண்டு சோபை
ஏழுசுரங்கள் பலதுக்கம் விடமுண்டாமே" - **சதக நாடி**

Vaathakabam, Kabam Naadi could be felt in ulceration condition.

NEERKURI

"வந்த நீரிக்கரி எடை மணம் நுரை எஞ்சலென்
றைந்தியலுளவை யறைகுது முறையே." - தேரர்நீர்குறி நெய்குறி நூல்

Before the day of urine examination instruct to the take balanced diet and good sleep. After waking up in early morning, the first urine should be collected in a clear wide mouthed glass container and is subjected to analysis of *Neerkuri* within $1^{1/2}$ hours

NEIKURI

The collected specimen should be kept in open container or glass bowl.it is to be examined under direct sun light, without shaking of vessel. Then add one drop of gingili oil without disturbing the urinary specimen. The *Neikuri* was noted in direct sunlight and conclude the diagnosis.

"புண்ணிர் மேகப்புண்கண் மாப்பிணி
நண்ணில் நித்திய நாதியம் ஆமெனும்." - **நித்திய நாதியம்**

In diabetic ulcer, the collected urine sample appears in red color.

LINE OF TREATMENT:

- *Neekam* (Treatment)
- *Niraivu* (Rejuvenation)
- *Kaapu* (Prevention)

***NEEKAM* (TREATMENT)**

- *Viresanam*
- Internal medicine
- External medicine

Viresanam

Viresina sigichai mainly used to equalize derangement of three biological humours and also restoring the physiological constituents of *Thathu*.

'துகின்ற மலக்கல்டை யொழிய வைத்தால்
உடலிலுள்ள வாதையெலா மொடுங்கிப் போகும்'

According to the text of siddha vaithiya thirattu,

இடுகண்ணிற் கடுகிற் பாதி
வீங்குகற் றாழஞ் சோறு
வடிதயிர் சந்தனங்கள்
வைத்துநீ கட்ட மாறும்
படுபரும் **பிளவை** வாழை
பகரை யாப்புப் **புண்கள்**
உடலுறு சிலந்தி கொல்லா
முமிழ் நீரிற் பூச நன்றே **- சித்த வைத்திய திரட்டு**

In viranam, *Agasthiyar kulambu* can be applied externally and internally it can be given with *Sangankuppi Charu*.

***Anubanam*:**

அனுபானத்தாலே யவிழ்தம் பலிக்கும்
இனிதான சுக்கு இஞ்சி - பினிமுதுகால்
கோமயம்பால் முலைப்பால் கோநெய்தேன் வெற்றிலைநீர்
ஆமிதையா ராய்ந்து செய்யலாம் **- தேரையர் வெண்பா**

***Pathiyam* (Dietary Regimen):**

In siddha aspect treatment can be given based on taste whichneutralize the three biological humours and restore the physical constituents of the body. Arusuvai and thirithodam are interlinked. Predominance of *kaatru*, and *thee* element express the pungent taste, *man* and *kaatru* element express the *thuvarpu* taste, both are having the hot potency. In suvai basis pungent and astringent taste which cures the ulcer formation, skin disease etc. As the hot potency has the action of curing ulcers, pungent and astringent taste with hot potency helps in curing ulcers.

***Niraivu*(Rejuvenation)**

The substance used for neutralising the three biological humours there are;

ஒன்றிய வாதபித்தம் கபமிவை யுயராவண்ணம்
நன்றது கறிகளெல்லாம் நாளுமே சமைப்பாராய்ந்தோர்
தின்றிடு மிளகு மஞ்சள் சீரகமுயர்ந்த காயம்
வென்றிகொள் சுக்கோடேலம் வெந்தய முள்ளி சேர்ந்தே

- பதார்த்த குணசிந்தாமணி

Kaapu (Prevention)

Ideal measures mentioned in the siddha classical text *Pathartha guna chinthamani* for for healthy living as below,

திண்ணமிரண்டுள்ளே சிக்க வடக்காமற்
பெண்ணின்பா லொன்றைப் பெருகாமல் உண்ணுங்கால்
நீர்சுருக்கி மோர்பெருக்கி நெய்யுருக்ககி யுண்பவர்தம்
பேருரைக்கிற் போமே பிணி. - **பதார்த்த குணசிந்தாமணி**

ஆறுதிங்கட் கொருதடவை வமன மருந் தயில்வோம்
அடர் நான்கு மதிக்கொருகாற் பேதியுறை நுகர்வோம்
தேறுமதி யொன்றக்கோர் தரநசியம் பெறுவோம்
திங்களரைக் கிரண்டுதரஞ் சவரவிருப் புறுவோம்
வீறுசதுர் நாட்கொருகால் நெய்முழுக்கைத் தவிரோம்
விழிகளுக்குஞ் சனமூன்று நாட்கொறுகா லிடுவோம்
நாறுகந்தம் புட்பமிவை நடுநசியில் முகரோம்
நமனார்க்கிங் கேதுவை நாமிருக்கு மிடத்தே.

LITERATURE REVIEW OF *MADHUMEGA VIRANAM* IN MODERN ASPECT

Diabetes mellitus (DM) is a complex disease affecting almost all the vital organs in the body. Diabetic foot is one of the most significant and devastating complication of diabetes, foot is affected by ulceration that is associated with neuropathy and peripheral arterial disease of the lower limb in a patient with diabetes.

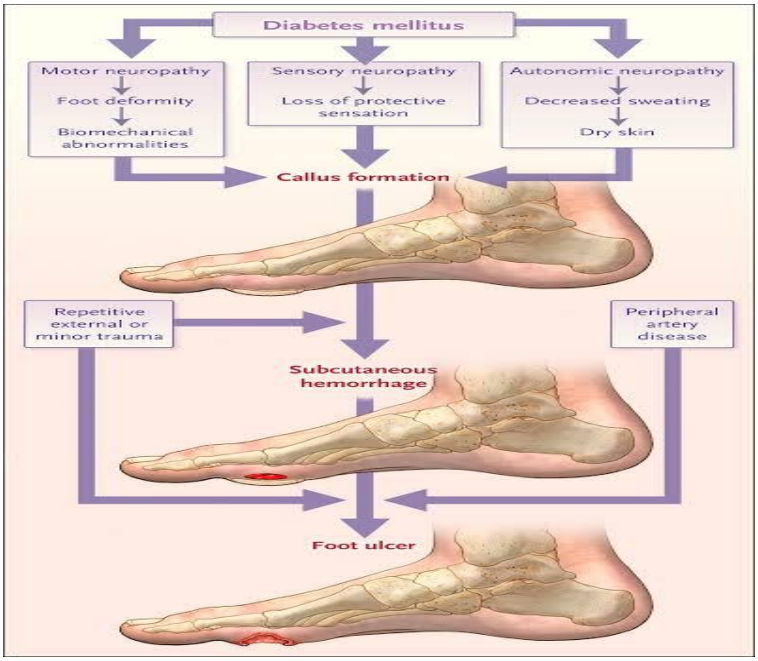
TYPES OF DIABETIC FOOT ULCERS

Diabetic foot ulcers are divided into 2 groups, namely:

- **Neuropathic ulcer** Feet is warm; perfusion is still good with pulsation still palpable, perspiration is reduced, skin dry and cracked.
- **Neuroischemic ulcer** Feet is colder, not palpable pulsation, thin skin, and smooth and without hair, subcutaneous tissue atrophy, intermittent claudication and rest pain may not be present due to neuropathy.

PATHOPHYSIOLOGY

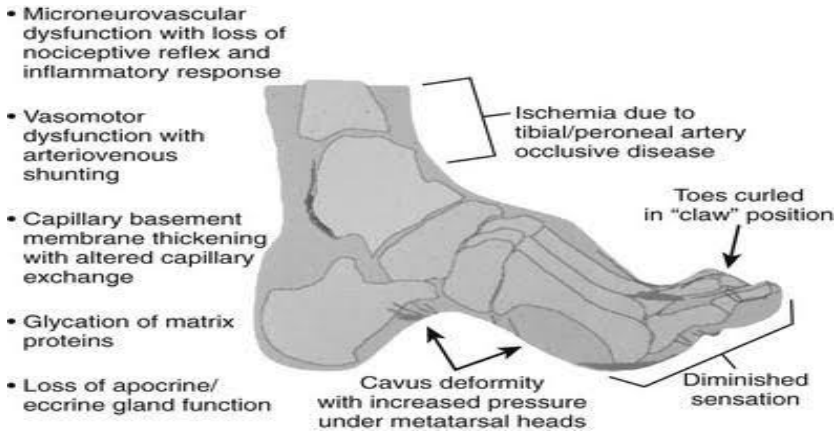
The aetiology of a diabetic foot ulcer (DFU) is multifaceted. No single risk factor is responsible for a foot ulcer. Several components cause added together to create a sufficient impact for ulceration.



NEUROPATHY

Peripheral neuropathy (loss of sensation) frequently occurs 20% at the time of diagnosis and about 8- 12 years after developing type 2diabetes, and is the permissive factor in ulcer development. Diabetic peripheral neuropathy is an impairment of normal activities of the nerves throughout the body and can alter autonomic, motor, and sensory functions. The reported prevalence of diabetic peripheral neuropathy ranges from 16% to as high as 66%.More than 60% incidence of foot ulcers caused by Neuropathy and affects patients with both type 1 and type 2 DM. The hyperglycemic conditions increased the production of some enzyme such as aldose reductase and sorbitol dehydrogenase. These enzymes convert glucose into sorbitol and fructose. As these sugar products accumulate, the synthesis of nerve cell myo inositol is decreased, affecting nerve conduction. Further, hyperglycemia-induced microangiopathy conducts the reversible metabolic, motor and sensory nerves, immunologic and ischemic injury of autonomic. It induces low peripheral sensation and compensation fine vasomotor control of the pedal circulation and the nerve innervations of small muscles of the foot. When the nerve gains hurt, the patient is at a high risk of a minor injury without spotting it until it makes an ulcer. The sensory loss is increased up to seven-fold, oppose to non-neuropathic patients with diabetes. DM also influences leading to dryness and fissuring of skin, making it prone to infection, the autonomic nervous system. The microcirculation of skin is controlled by the autonomic system. These changes assist in the expansion of gangrene, ulcers, and limb loss.

CHARCOT NEUROARTHROPATHY



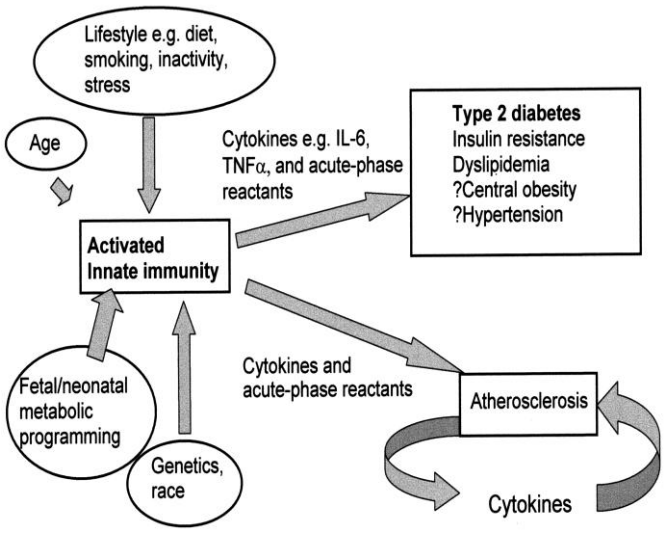
VASCULOPATHY

Hyperglycemia causes endothelial cell dysfunction and smooth cell abnormalities in peripheral arteries. Endothelial dysfunction is the most serious impairment affecting microcirculation, owing to changes in the proliferation of endothelial cells, thickening of the basement membrane, decreased synthesis of nitric oxide, increased blood viscosity, alterations in micro vascular tone and decreased blood flow. Nitric oxide is synthesized by endothelial cells which influence vasodilation and secure the blood vessels from the endogenous wound. Accordingly, in hyperglycemia, perturbation of the physiological properties of nitric oxide usually anticoagulation regulates the endothelial homeostasis, smooth muscle cell proliferation and antioxidant capacity, leukocyte adhesion. Endothelium-derived vasodilators and nitric oxide decreased. It leads to the propensity for atherosclerosis, constriction of the blood vessels and eventually leading to ischemia. Ischemia also happens, in fact, the attendance of palpable pedal pulses. The microcirculation is also disturbed due to arteriolar-venular shunting, reducing the blood circulation to the area of need. Hyperglycemia in DM also associated with an increase in thromboxane A2 leading to plasma hypercoagulability.

IMMUNOPATHY

The immune system of a patient with diabetes is much weaker than the healthy people. Thus, foot infection in a patient with diabetes is a limb-threatening and debilitating condition. The hyperglycemic state causes an elevation of pro-inflammatory cytokines and impairment of polymorph nuclear cell functions like chemo taxis, adherence, phagocytosis and intracellular killing.The immune system is compromised by lowered leukocyte activity, inappropriate inflammatory response and the disruption of cellular immunity (inhibition of fibroblast proliferation and impairment of the basal layer of keratinocytes, reducing epidermal cell migration).Leukocyte phagocytosis was significantly reduced in patients with poorly controlled diabetes, and improvement of microbiocidal rates was directly correlated with correction of hyperglycemia. Decreased chemo taxis of growth actors and cytokines, coupled with an excess of metalloproteinase, impede normal wound healing by creating a prolonged inflammatory state. This metabolic dysfunction impairs the synthesis of proteins, fibroblasts, and collagen, and further systemic deficiencies are propagated which lead to nutritional compromise. Research indicates impairment of the immune system with serum

glucoselevels ≥150 ml/dl. Patients with diabetes tolerate infection poorly and infection adversely affects diabetic control. High blood glucose is a good medium for the growth of bacteria, mainly aerobic gram-positive cocci like *S. Aureus* and *β*-hemolytic streptococci but in one research conducted in India, gram-negative aerobes were the common microorganisms in the diabetic foot. Muscles sheaths, tendons, the soft tissues of foot like plantar aponeurosis, and fascia cannot resist infections.

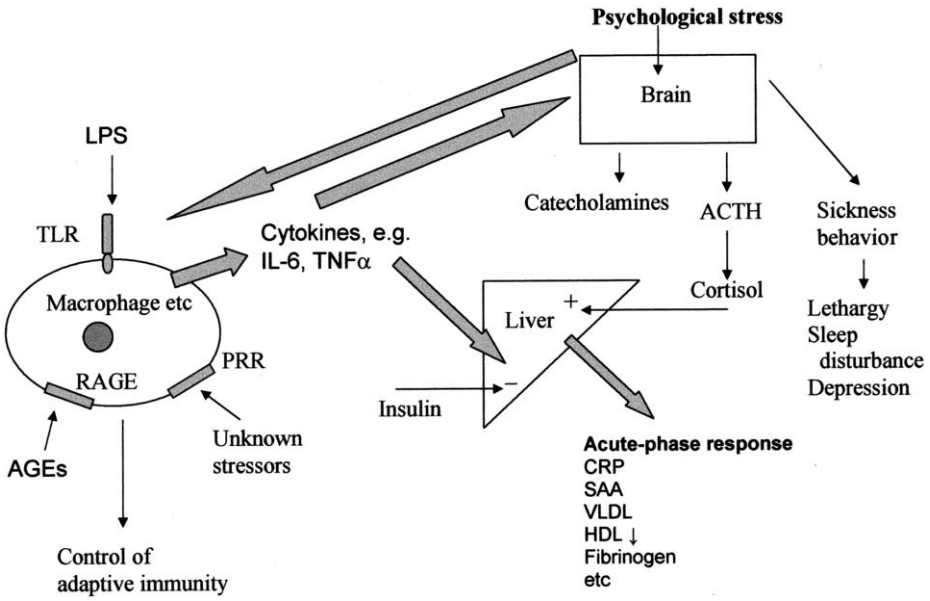


MECHANICAL STRESS

In people with neuropathy, minor trauma (e.g. from ill-fitting shoes, walking barefoot or an acute injury) can precipitate ulceration of the foot. Loss of sensation, foot deformities, and limited joint mobility can result in abnormal biomechanical loading of the foot. This produces a high pressure in some areas, to which the body responds with thickened skin (callus).Usually, ulcers happen in the plantar of great toe and heel and unfitting shoes (which are the source of trauma) can cause ulcers on the dorsal aspect. Hence neuropathic foot ulcer formation in patients with diabetes has a complex multifactorial aetiopathogenesis wherein areas of high pressure complimented by peripheral neuropathy and associated skin changes lead to ulcer formation.

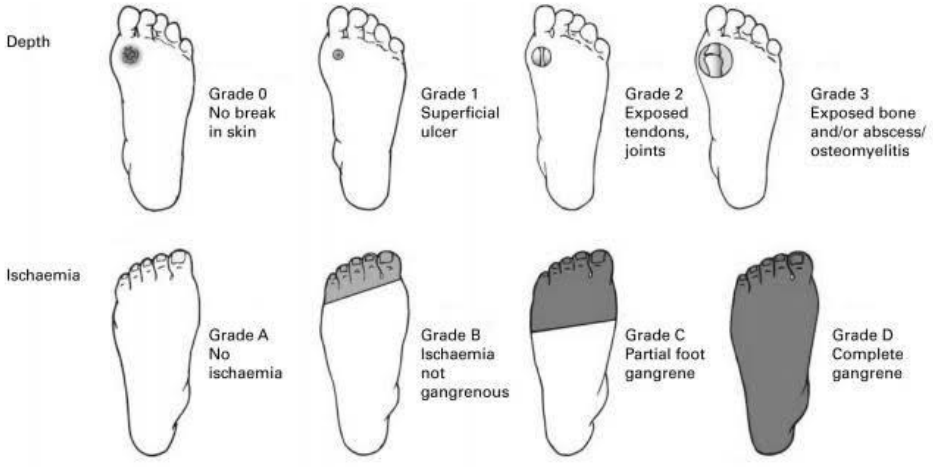
NEUROARTHROPATHY

A chronic painless progressive degenerative arthropathy is popular as Charcot neuroarthropathy (CN) resulting from the disruption in sensory innervations of the affected joint. Charcot foot is an insidious, destructive, and progressive pathological condition that affects the foot bones and leads to a deformity that may cause ulcer formation and subsequent disability. The development of Charcot's foot is characterized by subluxation and joint dislocation, osteolysis and bone fragmentation, and soft tissue edema. The demolition of the autonomic nervous system because of DM causes an upgrade in local blood provides and the resting blood flow is higher than in the normal patient. The incidental elevated in blood flow due to calcium to dissolve, leading the osteoclastic activity of the bone and damaging the bone. Another theory is that the repeated small trauma to the insensate joints conducts to fracture and disintegration. The pro-inflammatory cytokines production conducts to uncontrolled osteolysis in CN.



The cytokines like tumor necrosis factor-α and interleukin-1β increase the expression of receptor activator of nuclear factor-κb (RANKL), which in turn makes maturation of osteoclasts by causing the production of nuclear factor-κb. The hallmark deformity associated with this condition is a midfoot decay, also known as “rocker-bottom” foot. There might be hallux valgus

Deformity and lose bodies in the joint cavity. The deformities connected with CN also predispose to recurrent ulcerations.

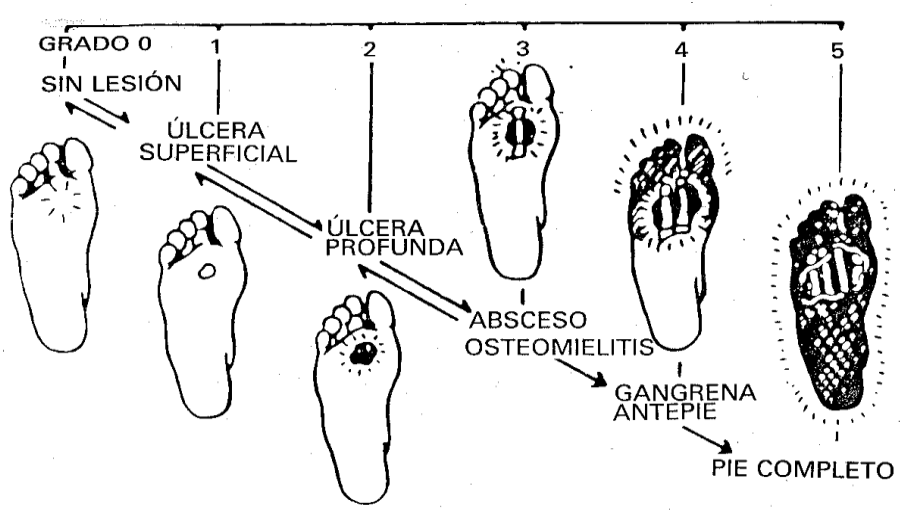


EPIDEMIOLOGY

In people with diabetes, and is the most important precursor for lower-extremity amputations. By 2015 prevalence data from the International Diabetes Federation; it estimated that, annually, foot ulcers develop in 9.1 million to 26.1 million people with diabetes worldwide.

CLASSIFICATION

There are many classifications of the diabetic foot. However, the most commonly used classification systems are the Wagner-Ulcer Classification system and the University of Texas Wound



CAUSES:

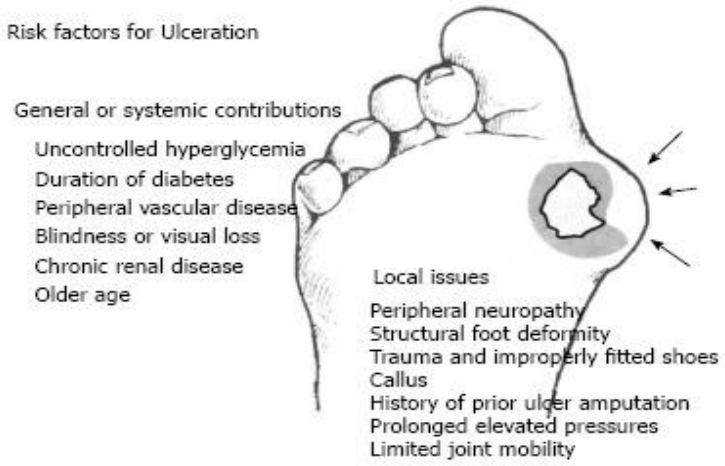
- Poor blood circulation
- High blood sugar level
- Nerve damage
- Minor trauma

CLINICAL FEATURES:

- Swelling, discoloration, and warmth around the wound
- Foul-smell discharge from the wound
- Pain and firmness when the wound is touched
- Callus or thickened skin present around the ulcer
- Fever and chills in advanced stage of foot ulcer
- Painless ulcer or only mildly painful unilateral swelling of ulcer
- Paresthesia
- Cellulitis
- Osteomyelitis
- Gangrene and amputation.

RISK FACTOR:

Previous studies have identified smoking as a risk factor for diabetic foot ulcers because daily tissue hypoxia may cause vascular and neuropathic disorders in the lower extremities of diabetic patients.The contribution of obesity to the risk of diabetic foot ulceration is inconclusive. Previous studies have revealed that obesity might associate with diabetic foot ulcers. However; there are also prospective studies showing that BMI has no significant correlation with a diabetic foot ulcer. Zang *et al.* in their study suggested that patients with diabetic foot ulceration had lower BMIs than patients without a diabetic foot, and most BMI levels in our study ranged from 25 to 30 kg/m2. These results suggested that the association between BMI ranging from 25 to 30 kg/m2 and diabetic foot ulcer requires further research. Their study also suggested that diabetic foot was more common in male diabetic patients than female patients. One explanation of this gender difference might be the involvement in increased physical work in males



TREATMENT

The gold standard for diabetic foot ulcer treatment includes debridement of the wound, management of any infection, revascularization procedures when indicated, and off-loading of the ulcer. Other methods have also been suggested to be beneficial as add-on therapies, such as hyperbaric oxygen therapy, use of advanced wound care products, and negative pressure wound therapy (NPWT).

Negative-Pressure Wound Therapy

Negative-pressure wound therapy (NPWT) has emerged as a new treatment for diabetic footulcers. It involves the use of intermittent or continuous sub atmospheric pressure through a special pump (vacuum-assisted closure) connected to a resilient open-celled foam surface dressing covered with an adhesive drape to maintain a closed environment. The pump is connected to a canister to collect wound discharge and exudate. Experimental data suggest that NPWT optimizes blood flow, decreases tissue edema, and removes exudate, pro inflammatory cytokines, and bacteria from the wound area. It should be performed after debridement and continued until the formation of healthy granulation tissue at the surface of the ulcer. Currently, NPWT is indicated for complex diabetic foot wounds; however, it is contraindicated for patients with an active bleeding ulcer. Two small studies and one larger study provide some encouraging data concerning the possible benefit of NPWT in the healing rate and time of diabetic foot ulcers. However, more randomized trials are needed in order to confirm these results.

Hyperbaric Oxygen

There is strong evidence that fibroblasts, endothelial cells, and keratinocytes are replicated at higher rates in an oxygen-rich environment. Moreover, leukocytes kill bacteria more effectively when supplied by oxygen. It is also known that fibroblasts from diabetic individuals show diminished cell turn over in comparison with those from non-diabetic persons. Based on these data, the idea was that the administration of oxygen at high concentrations might accelerate wound healing in diabetes. Treatment with hyperbaric oxygen therapy involves the intermittent administration of 100% oxygen at a pressure greater than that at sea level. It is performed in a chamber with the patient breathing 100% oxygen intermittently while the atmospheric pressure is increased to 2–3 atmospheres for duration of 1–2 h.

PREVENTION:

- Special foot care to prevent foot ulcer to poor
- Patients should not walk around barefoot, but use proper foot wears.
- Control blood sugar level.

DIABETIC FOOT CARE:

- Inspect your feet daily
- Wash your feet in luke warm
- Make sure to carefully dry between the toes
- Moisture your feet but not between your toes
- Never cut corns or callus
- Wear clean and dry socks
- Never walk in barefoot. Not even at home

DRUG REVIEW

INTERNAL MEDICINE

GANDHI MATHIRAI

Gandhagam (*Sulphur)*

Kaatupagal (*Momorandica dioica*)

Karunai kizhangu (*Typhonium trilobatum*)

Kadukai (*Terminalia chebula)*

Sembai (*Sesbania sesban*)

GANTHAGAM

English name **:** Sulphur

Organoleptic character

Taste **:** Kaippu, Thuvarpu

Potency **:** *Veppam, Thatpam*

பொது குணம்:

"நெல்லிக்காய்க்கந்திக்குநீள் பதினெண்குட்டமந்தம்
வல்லைகவிசை குன்ம வாயுகண்ணோய்-பொல்லா
விடக்கடி வன்மேகனோய் வீறுசுரம்பேதி
திக்கிரசுணீகபம்போந்தேர்"

ACTION:

- Laxative
- Tonic
- Antiseptic
- Diaphoretic
- Cholagogue

KAATUPAGAL

Botanical name **:** *Momordica dioica*

Family **:** Cucurbitaceae

Parts used **:** Fruit

Organoleptic characters

Taste **:** Bitter

Potency **:** Hot

Division **:** Pungent

ACTION

- Astringent
- Stimulant
- Expectorant

CHEMICAL CONSTITUENTS

Calcium, iron, zinc, manganese, iodine, chromium, phytic acid, total phenolic compound, alkaloids, flavonoids, steroids, triterpinoids, saponins.

PHARMACOLOGICAL ACTIVITY

- Wound healing activity
- Anti-microbial activity
- Anti-diabetic activity
- Anti-oxidant activity
- Analgesic activity
- Neuro protective
- Anti-cancer
- Immunomodulator
- Anti lipidemic

The antioxidant activities of methanol and aqueous extract of fruits were analyzed and the presence of phenolic compounds, flavonoids, sterol, alkaloids, amino acids, and so forth, were found. Among those compounds, due to the presence of flavonoids, its fruit was reported as a potent antioxidant.Anti-diabetic specifically oral hypoglycemic effects of Momordica dioica in rat model was screened by Fernandopulle et al.Gupta et al. investigated the antidiabetic and renal protective effect of Momordica dioica methanolic extract (MDMtE) in streptozotocin-treated diabetic rats. Evaluated hexane and methanolic extract of fruit pulp mediated, anti-inflammatory activities.

KARUNAI KIZHANGU

Botanical name **:** *Typhonium trilobatum*

Family **:** *Araceae*

Parts used **:** Rhizome

Organoleptic characters

Taste **:** Pungent

Potency **:** Hot

Division **:** Pungent

ACTION:

- Stimulant
- Astringent

CHEMICAL CONSTITUENTS:

The root contain proteins and inorganic substance Ca, P, I, Fe, Na, K; thiamine, niacin, carotene, folic acid sterols and beta sitosterol.

PHARMACOLOGICAL ACTIVITY:

- Wound healing activity
- Anti-oxidant activity
- Anti-inflammatory
- Anti-depressant
- Thrombolytic activity

Ethanol extract of Typhonium trilobatum roots has antioxidant activity. The thrombolytic activity of the Typhonium trilobatum root extracts were carried out using a simple and rapid in vitro clot lysis model.Xylene-induced ear edema in rats was used to assess anti-inflammatory activity of the plant extract.The ethanolic leaf extract of T. trilobatum was shows analgesic activity using acetic acid-induced writhing method.

KADUKKAI

Botanical name **:** *Terminalia chebula*

Family **:** *Combretaceae*

Parts used **:** Fruit

Organoleptic characters

Taste **:** Pungent

Potency **:** Hot

Division **:** Sweet

பொது குணம்

தாடை கழுத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுதற் பேதிமுடம்-ஆடையெட்டாத்
தூலமிடி **புண்**வாத சோணிகா மாலையிரண்
டாலமிடி போம்வரிக்கா யால்

ACTION:

- Astringent
- Alterative
- Purgative

CHEMICAL CONSTITUENTS:

Chebulic acid, palmitic acid, stearic acid, oleic acid, linoleic acid and anthroquinone derivatives, tannic acid, gallic acid.

PHARMACOLOGICAL ACTIVITY:

- Antibacterial
- Antifungal
- Antiviral
- Anti-Carcinogenic
- Antioxidant
- Hypolipidemic
- Hepatoprotective
- Cardio Protective
- Anti-Diabetic
- Wound healing activities

The extract of Terminalia chebula shows broad spectrum activitiy.ethanolic extract of Terminalia chebula showed antimicrobial activity against methicillin-resistant Staphylococcus aureus It has stronger antioxidant activity than alpha-tocopherol. HPLC analysis with diode array detection indicated the presence of hydroxybenzoic acid derivatives, hydroxycinnamic acid derivatives, flavonol aglycones and their glycosides, as main phenolic compounds.The chloroform extract of Terminalia chebula seeds produced dose-dependent reduction in blood glucose of diabetic rats compared with standard drug glibenclamide in both short and long term study T. chebula showed improvement to stimulate fibroblast function, enhance synthesis of glycoseminoglycans and deposition of collagen. Thus, it offers a distinct advantage to wound healing.

SEMBAI

Botanical name **:** *Sesbania sesban*
Family **:** Fabaceae
Parts used **:** Leaf

Organoleptic characters

Taste **:** Bitter
Potency **:** Hot
Division **:** Pungent

ACTION:

- Stimulant
- Astringent
- Expectorant

CHEMICAL CONSTITUENTS:

Oleanolic acid, beta-D-galactopyranoside,saponin,anthocyanidins.triterpenoids, starches, vitamins, amino acids, proteins, tannins, saponins glycosides and steroids. Blossoms contain cyanidin and delphinidinglucosides ,Alpha-ketoglutaric, oxaloacetic and pyruvic acids. Leaf and unit contains ampesterol cholesterol, beta-sitosterol, triterpenoids, proteins and tannins. Bark and stem contains glucose, fructose, erithryrol, arabinitol, myo-inositol.

PHARMACOLOGICAL ACTIVITY:

- Anti-oxidant
- Anti-inflammatory
- Anti-diabetic
- Wound healing activity

The antioxidant activity of the Sesbania sesban acidified methanol extract showed high scavenging activity of 84% at lower concen-tration (1mg) along with the standard BHT (37.65%) and Ascorbic acid is considered as the positive control. The aqueous leaves extract of Sesbania sesban was evaluated for its antidiabetic potential on normal and streptozotocin (STZ)-induced diabetic rats. Anthocyanins from Sesbania sesban flower petals exhibited a dose dependent free-radical scavenging activity against DPPH radical, superoxide anions and hydroxyl radical.

External medicine
SAGALA RANAGALUKUM KALIMBU:

Lingam(*Cinnabar*)
Miruthar singi(*Lead Ore*)
Rasakarpooram(*Calomel*)
Vellai kungiliyam(*Vateria indica*)
Kadukkai(*Terminalia chebula*)
Masikkai(*Quercus infectoria*)
Thandrikkai(*Terminalia bellerica*)
Kaichukkatti*(Catechu*)

LINGAM

English name : cinnabar

பொது குணம்:

"பேதிசுரஞ் சந்நி **பெருவிரண** நீரொடுத
காதகடி காசங் கரப்பான்**புண்**-ணோத
வுருவிலிங்க சங்கதமா யூறுகட்டி யும்போங்
குருவிலிங்க சங்கமத்தைக் கொள்."

ACTION

- Alterative

INDICATION:

- Chronic non healing ulcer
- Skin diseases
- Arthritis
- Diarrhea
- Fever
- Frequency of micturition
- Eczema
- Cough

MIRUTHAR SINGI

English name : Lead Ore

பொது குணம்:

"மிருதார சிங்கெனவே மெல்லவுரைத்தாலும்
முருவார் புடைகரப்பா னோடு-மொருவிதமோ
சாலச் சிரங்கு**புண்ணுாந்** தப்பாம லாறிவிடு\
வேலொத்த கண்மயிலே விள்"

ACTION:

- Astringent
- Refrigerant
- Anthelmintic

TYPE:

It has three types there are *Miruthar Singi*, *Raththa Singi*,*Aema Singi*

INDICATION:

- Chronic skin diseases
- Chronic ulcer

RASAKARPOORAM

English name **:** Calomel

பொது குணம்

"இடைவாத சூலை யெரிசூலை குன்மந்
தொடைவாழை வாதமாஞ் சோணி-யிடையாதோ
வொக்கரச கர்ப்பூர மொன்றே யளவொடுநல்
இக்குவெல்லத் தேழுநா ளீ."

Organoleptic characters

Taste **:** Salt, Pungent
Potency **:** Hot
Division **:** Pungent

INDICATION

- Low back pain
- Gastric ulcer
- Chronic non healing ulcer
- Sinusitis
- Arthritis
- Diabetes
- Constipation
- Head ache

VELLAI KUNGILIYAM

Botanical name **:** *Vateria indica*
Family **:** Dipterocarpaceae
Parts used **:** Resin

Organoleptic characters

Taste **:** Bitter
Potency **:** Hot
Division **:** Pungent

ACTION:

- Stimulant
- Diuretic
- Expectorant

பொது குணம்

வெள்ளை யளித்த **விரணநா** பிக்கமலத்
தொள்ளைவிர ணம்மேகந் தோற்றுகினும்-உள்ளே
வருவரசனைமேற்**புண்** வரினும்ஞ் சுவேதச்
சருவரச மேற்பழியைச் சாற்று. **- தேரையர் குணவாகடம்**

INDICATION:

- Cystitis
- Fissure in ano
- Internal hemorrhoids
- Ulcer

CHEMICAL CONSTITUENTS

Resin is a complex mixture of several triterpene hydrocarbons, ketones, alcohols and acids, along with small amounts of sesquiterpenes.

PHARMACOLOGICAL ACTIVITY

- Anti-inflammatory
- Anti tumour activity
- Anti-microbial activity

Vateria indica leaves have anti-inflammatory activity which may be due to the presence of alkaloids, steroids and glycosides.

KADUKKAI

Botanical name **:** *Terminalia chebula*

Family **:** *Combretaceae*

Parts used **:** Fruit

பொது குணம்

தாடை கழுத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுதற் பேதிமுடம்-ஆடையெட்டாத்
தூலமிடி **புண்**வாத சோணிகா மாலையிரண்
டாலமிடி போம்வரிக்கா யால்

Organoleptic characters

Taste **:** Pungent

Potency **:** Hot

Division **:** sweet

ACTION:

- Astringent
- Alterative
- Purgative

CHEMICAL CONSTITUENTS:

Chebulic acid, palmitic acid, stearic acid, oleic acid, linoleic acid and anthroquinone derivatives, tannic acid, gallic acid.

PHARMACOLOGICAL ACTIVITY:

- Antibacterial
- Antifungal
- Antiviral
- Anti-Carcinogenic
- Antioxidant
- Hypolipidemic
- Hepatoprotective
- Cardio Protective
- Anti-Diabetic
- Wound healing activities

The extract of Terminalia chebula shows broad spectrum activitiy.ethanolic extract of Terminalia chebula showed antimicrobial activity against methicillin-resistant Staphylococcus aureus It has stronger antioxidant activity than alpha-tocopherol. HPLC analysis with diode array detection indicated the presence of hydroxybenzoic acid derivatives, hydroxycinnamic acid derivatives, flavonol aglycones and their glycosides, as main phenolic compounds.The chloroform extract of Terminalia chebula seeds produced dose-dependent reduction in blood glucose of diabetic rats compared with standard drug glibenclamide in both short and long term study T. chebula showed improvement to stimulate fibroblast function, enhance synthesis of glycoseminoglycans and deposition of collagen. Thus, it offers a distinct advantage to wound healing.

MASIKKAI

Botanical name **:** *Quercus infectoria*
English name **:** Magic nuts
Family **:** Fagaceae
Parts used **:** Galls, bark

பொது குணம்

அக்கரங்கள் போக்கிவிடும் மாறாத வெப்பகற்றும்
மெய்க்குறுதி மாசிக்காய் மென்மேலும்-தக்கதொரு
பாலர்கண நோய்போக்கும் பன்மேக முந்தொலைக்கும்
வேலனைய கண்ணய் விளிம்பு. **- அகத்தியர் குணவாகடம்**

ACTION:

- Astringent
- Alterative
- Hemostatic
- Tonic

CHEMICAL CONSTITUENTS:

Tannic acid,2-4% gallic acid, ellagic acid,sugar,starch,gallo tannic acid,50-70% tannin.

PHARMACOLOGICAL ACTIVITY:

Quercus infectoria antibacterial activity was quite good, Proteus vulgaris showed very good results (20 mm) of MIC & minimum of Enterobacter aerogenes. The antioxidant activity of Quercus infectoria in methanolic extract using DPPH assay method shows appreciable activity comparable to standard ascorbic acid. The wound healing and repair is accelerated by applying Quercus infectoria which was high-lighted by the full thickness coverage of the wound area by an organized epidermis in the presence of mature scar tissue in the dermis.

THAANDRIKKAI

Botanical name **:** *Terminalia bellerica*
English name **:** Belleric myrobalan
Family **:** Combretaceae
Parts used **:** Fruit,bark

பொது குணம்

சிலந்தி விடம் காமியம்ப் புண் சீழான மேகங்
கலந்துவரும் வாதபித்தங் காலோ-டலர்ந்துடலில்
ஊன்றிக்காய் வெப்ப முதிரபித் துங்கரக்குந்
தான்றிக்காய் கையிலெடுத் தால்

ACTION:

- Astringent
- Expectorant
- Laxative
- Tonic

PHARMACOLOGICAL ACTIVITY

- Anti-oxidant
- Anti-inflammatory
- Wound healing
- Anti-microbial

Ramesh Kumar et al demonstrated that in vitro assessment of the antioxidant activity of ethanolic fractions of Terminalia bellerica to scavenge 2, 2- Diphenyl-1-picrylhydrazyl (DPPH) and highly reactive hydroxyl radicals showed that the semi pure compounds present in the fractions are useful potential source of antioxidants.25 . M.C.Babu et al; demonstrated that administration of T. belerica extract did not have any significant effect on serum glucose level in alloxan diabetic rats during first five days but started reducing from 6^{th} day onwards .On 9^{th} day when compared with that of control diabetic animals serum glucose in extract treated animals was found to be reduced to 54% .

KAAICHUKATTI

Botanical name **:** *Arecha catechu*

Family **:** Palmaeae

Parts used **:** Seed, extract, root, leaves

பொது குணம்

களிப்பாக்குத் தின்றக்காற் கண்டதுட் கோழை
யொளிப்பாபாகக் கட்டுமிஃதுண்மை-தளிர்ப்பான
பித்த அரோசகம் போம் பேதிமிக உண்டாகுஞ்
சித்த மகிழ்ச்சியுறுஞ் செப்பு. **- அகத்தியர் குணவாகடம்**

ACTION:

- Stimulant
- Astringent
- Toenifuge

PHARMACOLOGICAL ACTIVITY

- Anti-inflammatory activity
- Anti-oxidant
- Anti-diabetic
- Anti-microbial

Chempakam B et al;has reported that arecoline a major constituent of Areca catechu havehypoglycaemic activity in an animal model of diabetes upon subcutaneous administration. The Subcutaneous administration of alkaloid fraction of Areca catechu (0.05_/0.5 mg/kg) in alloxanized rabbits (140 mg/kg) showed significant hypoglycaemic effect lasting for 4/6 hours 9. Inokuchi J, Okabe H et al describes that Areca tannin inhibits the pressure response angiotensin I and II thus showing a regulatory effect on blood pressure.

MATERIALS AND METHODS

COLLECTION OF RAW DRUGS:

The required raw drugs for the preparation of the trial medicines were collected from a well reputed country raw drug shop**.**

RAW DRUGS IDENTIFICATION AND AUTHENTICATION:

The mineral raw drugs were identified and authenticated by Dr.visweshwaran M.D(s), Lecturer, Department of Gunapadam,National institute of siddha NIS/GUNAPADAM/ AU/ 2017/4. The Herbal raw drugs were identified and authenticated by Dr.D.Aravind M.D(s), Assistant professor, Dept. of Botany, National Institute of Siddha, Certificate no NISMB2892017. After that the raw drugs were purified as per siddha literature then the trial drugs prepared in Gunapadam laboratory of National Institute of Siddha.

INTERNAL DRUG:

GANDHI MATHIRAI:

INGREDIENTS OF GANDHI MATHIRAI:

Gandhgam	(*Sulphur)*
Kaatupagal	(*Momorandica dioica*)
Karunai kizhangu	(*Typhonium trilobatum*)
Kadukai	(*Terminalia chebula)*
Sembai ilia charu	(Sesbania sesban)

RAW DRUGS OF *GANDHI MATHIRAI*

SULPHUR

Terminalia chebula

Momordica dioica

Sesbania seaban

Typhonium trilobatum

METHOD OF PURIFICATION OF RAW DRUGS:

Purification of Gandhagam (*Sulphur):*

Sulphur is placed in an iron spoon. A small quantity of cow's butter is added and the spoon is heated till the butter melts; this mixture is immersed in inclined position in cow's milk. This procedure is repeated for 30 times to get purified sulphur. Each time, fresh milk is to be used. [Ref: Siddha Materia Medica (Mineral and animal kingdom) Page No: 253]

Purification of kadukkai (*Terminalia chebula*):

Remove the nut and use the outer covering of the drug.[Ref- Sarakugalin suthi muraigal pg.no 4]

METHOD OF PREPARATION :

Gandhgam	(*Sulphur)*
Kaatupagal	(*Momorandica dioica*)
Karunai kizhangu	(*Typhonium trilobatum*)
Kadukai	(*Terminalia chebula)*
Sembai ilia charu	(Sesbania sesban)

The above raw drugs will be ground with sembai leaf juice and made into 65mg pills.

GANDHI MATHIRAI

Dose: Ulunthalvu (65mg)

Vehicle: Thirikadugu Chooranam

Indication:

Pun(*DiabeticUlcer*), *13vagaisanni(*Delirium*),Swasakasam*(Bronchitis*),Kirani(*Diarrhoea*),vaayu*(Gastritis*),7 Vagai kasam(*Cough*),Vadham(*Pain*), Pandu(*Anemia),*18 Vagai Kuttam(*Skin Diseases*).*

EXTERNAL MEDICINE:

SAGALA RANAGALUKUM KALIMBU

INGREDIENTS OF SAGALA RANAGALUKUM KALIMBU:

- Lingam (*Cinnabar*)
- Miruthar singi (*Lead ore*)
- Rasakarpooram (*Calomel*)
- Vellai kungiliyam (*Vateria indica*)
- Kadukkai (*Terminalia chebula*)
- Masikkai (*Quercus infectoria*)
- Thandrikkai (*Terminalia bellerica*)
- Kaichukkatti *(Catechu*)

LINGAM

RASAKARPOORAM

MIRUTHAR SINGI

KAICHUKKATTI

KADUKKAI

MASIKKAI

THANDRIKKAI

VELLAIKUNGILIYAM

BUTTER

METHOD OF PURIFICATION OF RAW DRUGS

Purification of kadukkai (*Terminalia chebula*):

Remove the nut and use the outer covering of the drug.[Ref- Sarakugalin suthi muraigal pg.no 4]

Purification of Thandrikkai (*Terminalia bellerica*):

Remove the nut and use the outer covering of the drug.[Ref- Sarakugalin suthi muraigal pg.no 7]

Purification of Masikkai(*Quercus infectorius*):

Remove the nut and use the outer covering of the drug.[Ref- Sarakugalin suthi muraigal pg.no 13]

Purification of Lingam(Cinnabar):

The mineral drug soaked with lime juice for 2 hours.[Ref- Sarakugalin suthi muraigal pg.no 51]

Purification of Rasakarpooram(Calomel):

The mineral drug ties in cotton cloth and dipped with the decoction of pepper and betel leaf paste and boiled for 3 days [[Ref- Sarakugalin suthi muraigal pg.no53].

Purification of vellai kungiliyam(*Vateria indica*):

The herbal drug soaked with lime juice. [Ref- Sarakugalin suthi muraigal pg.no 4]

METHOD OF PREPARATION:

Miruthar singi	(*Lead Ore*)
Rasakarpooram	(*Calomel*)
Vellai kungiliyam	(*Vateria indica*)
Kadukkai	(*Terminalia chebula*)
Masikkai	(*Quercus infectoria*)
Thandrikkai	(*Terminalia bellerica*)
Kaichukkatti	*(Catechu*)

The above mentioned ingredients are taken in equal quantity and made into fine powder.

It’s mixed with sufficient quantity of cow’s butter and allows the paste into water for 24 hrs.

SAGALARANAGALUKUM KALIMBU

INDICATION : Kodumeiyana ranangal (***Madhumega viranam***)

DRUG STORAGE:

The trial drug ***Gandhi mathirai***is stored in clean and dry glass bottles and ***Sagala ranangalukum kalimbu***is stored in clean and dry bottles.

DISPENSING:

The tablet is given in packet. Paste is given in zip lock cover.

BIOCHEMICAL ANALYSIS:

Experimental procedure:

5 g of *Gandhi mathirai* was taken in a 250 ml of clean beaker and 50ml of distilled water was added to it. Then it was boiled well for about 10 min. Then it is allowed to cool and filtered in a 100 ml volumetric flask and made up to 100 ml with distilled water. This preparation is used for the qualitative analysis of acidic/ basic radicals and biochemical constituents in it.

Preparation of extract:

5gm of *Gandhi mathirai* is weighed accurately and placed in a 250ml clean beaker and 50ml of distilled water was added with it. Then it was boiled well for about 10 minutes. Then it was allowed to cool and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. The bio-chemical analysis of *Gandhi mathirai* was done at Biochemistry lab, National Institute of siddha, Chennai-47.

Preliminary test for Copper, Sodium, Silicate and Carbonate:

Test for Silicate:

A little (500mg) of the sample is shaken well with distilled water. b. A little(500mg) of the sample is shaken well with con. HCl/Con.H2So4. Sparingly /completely soluble indicates presence of silicate.

Action of Heat:

A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong. Evolution of white fumes/brown fumes indicates presence of carbonate.

Flame Test:

A small amount (500mg) of the sample is made into a paste with con.HCl in a watch glass and introduced into non-luminous part of the Bunsen flame. Presence of bluish green flame indicates the presence of copper.

Ash Test:

A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited. Presence of yellow color flames indicates the presence of sodium.

Test for Acid Radicals

Test for Sulphate:

2ml of the above prepared extract was taken in a test tube and 2ml of 4% dil. ammonium oxalate solution was added. Evolution cloudy appearance it indicates presence of sulphate.

Test for Chloride:

2ml of the above prepared extracts was added with 2ml of dil-HNO3 until the effervescence ceases off. Then 2 ml of silver nitrate solution was added. Presence of cloudy appearance indicates the presence of chloride.

Test for Phosphate:

2ml of the extract was treated with 2ml of con.HNo3 and 2ml of dil. ammonium molybdate solution. Evolution cloudy yellow appearance it indicates presence of phosphate.

Test for Carbonate:

2ml of the extract was treated with 2ml dil. magnesium sulphate solution.Evolution cloudy appearance it indicates presence of carbonate.

Test for Nitrate:

1gm of the substance was heated with copper turning and concentrated H2SO4 and viewed the test tube vertically down. Evolution of brown gas indicates presence of nitrate.

Test for Sulphide:

1gm of the substance was treated with 2ml of con. HCL. Evolution of rotten egg smell indicates the presence of sulphide.

Test for Fluoride & Oxalate:

2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated**.** Evolution of cloudy appearance indicates the presence of fluride and oxalate.

TEST FOR BASIC RADICALS

Test for Lead:

2ml of the extract was added with 2ml of dil. potassium iodine solution. Presence of yellow precipitate indicates the presence of lead.

Test for Copper:

One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame. Presence of blue colour flame indicates the presence of copper.

Test for Aluminium:

In the 2ml of extract dil. sodium hydroxide was added in 5 drops to excess. A mild characteristic change seen indicates the presence of aluminium.

Test for Iron:

a. a.To the 2ml of extract add 2ml of dil. ammonium solution.mild red colour appearance indicates the presence of iron.

b. To the 2ml of extract 2ml thiocyanate solution and 2ml of con HNo3 is added. Presence of blood red indicates presence of iron.

Test for Zinc:

In 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added. Appearance of white precipitate indicates the presence of zinc.

Test for Calcium:

2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution. Evolution of cloudy appearance indicates the presence of calcium.

Test for Magnesium:

In 2ml of extract dil.sodium hydroxide solution was added in drops toexcess. If the white precipitate is obtained indicates presence of magnesium.

Test for Ammonium:

In 2ml of extract 1 ml of Nessler's reagent and excess of dil. sodium hydroxide solution were added. Evolution of brown colour indicates the presence of ammonium.

Test for Potassium:

A pinch (25mg) of substance was treated with 2ml of dil. sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil. glacial acetic acid. Appearance of yellowish precipitate indicates the presence of potassium.

Test for Sodium:

2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner. Appearance of yellow colour indicates the presence of sodium.

Test for Mercury:

2ml of the extract was treated with 2ml of dil. sodium hydroxide solution. Appearance of yellowish precipitate indicates the presence of mercury.

Test for Arsenic:

2ml of the extract was treated with 2ml of dil. sodium hydroxide solution. Appearance of brownish precipitate indicates the presence of arsenic.

OTHER CONSTITUENTS

Test for Starch:

2ml of extract was treated with weak dil. iodine solution. Evolution of blue color indicates presence of starch.

Test for Reducing Sugar:

5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. Evolution of brick red colour indicates the presence of reducing sugar.

Test for the Alkaloids:

a. 2ml of the extract is treated with 2ml of dil. potassium iodide solution. Evolution of red color indicates the presence of alkaloid.
b. 2ml of the extract is treated with 2ml of dil.picric acid. Evolution of yellow colour indicates the presence of alkaloid.

Test for Tannic Acid:

2ml of extract was treated with 2ml of dil. ferric chloride solution. Appearance of black precipitate indicates the presence of tannic acid.

Test for Amino Acid:

2 drops of the extract was placed on a filter paper and dried well, and then 20ml of Burette reagent was added in it. Appreaence of violet colour indicates the presence of amino acid.

Test for Types of compound:

2ml of the extract is treated with 2ml of ferric chloride solution. Appearance of green color indicates the presence of oxy quinole epinephrine and pyrocatechol.

PHYTOCHEMICAL ANALYSIS

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:

Lead acetate test:

To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

To the test sample, 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of bluish green colour indicates the presence of anthocyanin.

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Toulene: Ethyl Acetate: Acetic Acid (1.5:1:0.5) after the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

STERILITY TEST BY POUR PLATE METHOD

Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

About 1ml of diluted test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (About 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.

Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculates with the test sample.

TEST	RESULT	SPECIFICATION	AS PER AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^{5}CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^{3}CFU/g	

NMT- Not more than

Test for Specific Pathogen

Methodology

About 5ml of test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol, Cetrimide) by spread plate method. The plates were incubated at 37^{o}C for 24 - 72h for observation. Presence of specific pathogen identified by their characteristic color with respect to pattern of colony formation in each differential media.

Abbreviation

Organism	Abbreviation
E-coli	*EC*
Salmonella	*SA*
Staphylococcus Aureus	*ST*
Pseudomonas Aeruginosa	*PS*

Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculated with the test sample.

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

SAFETY STUDIES:

The experimental studies on animals were conducted at National Institute of Siddha Tambaram, Sanatorium. (**IAEC NO:NIS/IAEC-III/10/29092016)**.

ACUTE TOXICITY STUDY:

Objective

The objective of "Acute oral Toxicity Study of **GM** on Female Wistar rats was to measure the toxicological studies of the drug when treated as a single dose. Animal should be observed for 14 days after the drug administration.

Test Guideline Followed:

Acute toxicity was conducted as per OECD- 423 Guideline with slight modification.

Materials and Methods:

The study was conducted on Female Wistar rats. These animals were selected because of the recommended rodent species for oral studies as per followed guideline Female wistar rats, 8-12 weeks old, 140-160gm body weight were used for the study. The body weight range should be within ± 20% of the mean body weight at the time of Randomization and grouping. The rats were purchased from The Tamilnadu Veterinary and animal sciences university, Madhavaram milk colony, Chennai-600051**.** Rodent pelleted feed RO purified water ad *libitum*. Animals will be kept in polypropylene cages and numbered.

Acclimatization:

The animals were selected after veterinary examination by the veterinarian; selected rats were kept under acclimatization for a week.

Randomization & grouping:

After acclimatization, Rats were randomized as control and GM treated group. Control group received distilled water and the treatment group was administered with **GM** 2gms/kg bd.wt.was a single dose p.o.

Identification:

Animals were housed with appropriate identification by colouring the fur with picric acid solution prepared in water and with cage cards.

Dose Preparation:

GM was added in polysorbate solution with distilled water and completely dissolved for oral administration. The dose was prepared of a required concentration before dosing by dissolving, in distilled water. It was mixed well.

Administration:

A single dose of the solution (2000mg/kg) was consecutively administered by oral gavage using intubation cannula. Food was withheld for another 4 hrs after dosing and administration of drug. As per the guideline the starting dose level was taken as 2000mg/kg body weight.

Observation period:

After drug administration observations were started to be recorded at the ½ hr, 1hour, 2hours, 4 hours on day one of dosing and twice daily after that for the next 13 consecutive days. At the 14th day, sensory reactivity to stimuli of different types was conducted. Auditory stimuli responses were measured by clicker sound from approximately 30 cm to the rats; visual stimuli response were measured with the help of shining pen light in the eye of rats and placing a blunt object near to the eye of rats. Response to proprioceptive stimuli was measured by placing anterior/dorsal surface of animals paw to the table edge. The responses of reactions for these three exercises were normal in animals belonging to both the controls as well as drug treatment dose groups. On day 15, the overnight fasted animals (water allowed *ad libitum*) were sacrificed and examine for gross pathological changes in the major internal organs.

REPEATED DOSE 90DAYS ORAL TOXICITY STUDY:

Objective:

Repeated dose 90days oral toxicity study was conducted as per OECD-408 Guideline. Animals should be observed for 90 days during the GM administration. Repeated dose 90days oral toxicity study give information on the health hazard likely to arise from frequent exposure over a relatively period of 90 days.

Test Guideline Followed

OECD 408 Method – chronic toxicity study (Repeated Dose 90-Days Oral Toxicity Study in Rats).

Good Laboratory Practices

The study was conducted following the principles of good Laboratory Practice as set for the Principles of Good Laboratory Practice, OECD, 1998.

Materials and methods

Test System Detail

Young adult Wister rats of 8-12 weeks old weighing 140-160 gms of both the sex was used for study. The body weight range should be within ± 20% of the mean body weight at the time of Randomization and grouping. Animals were housed in 4 groups (5/cage/sex) in polypropylene cages in a well-ventilated room under a temperature of 22 ± 3°C and 30 - 70% relative humidity, with a 12-hr light/dark artificial light cycle. The rats were purchased from The Tamilnadu Veterinary and animal sciences university, Madhavaram milk colony, Chennai-600051**.** Rodent pelleted feed RO purified water ad *libitum*. Animals will be kept in polypropylene cages and numbered.

Acclimatization

The animals were selected after veterinary examination by the veterinarian. All the selected animals were kept under acclimatization for a week.

Randomization & grouping:

One day before the initiation of treatment (last day of acclimatization), the selected animals were randomly grouped into 4 different groups containing 10 male animals and 10 female animals per group.

Numbering and Identification:

Animals were housed with appropriate identification by colouring the fur with picric acid solution prepared in water and with cage cards. The group no., cage no., sex of the animal and animal no. were identified as indicated below using cage label and body marking on the animals:

Numbering and identification of animals in chronic toxicity study

CAGE NO	GROUP NO	ANIMAL MARKING	SEX
1.	**I CONTROL**	1-10 11-20	Male Female
2.	**II LOW DOSE**	21-30 31-40	Male Female
3.	**III MID DOSE**	41-50 51-60	Male Female
4.	**IV HIGH DOSE**	61-70 71-80	Male Female

Doses:

The doses for the study were selected based on acute toxicity study. Following the period of fasting, the animals were weighed and then test drug was administered orally as single dose using a needle fitted on to a disposable syringe of approximate size at the following different doses.

Numbering and identification of animals in chronic toxicity study

CAGE NO	GROUP NO	ANIMAL MARKING	SEX
1.	**I CONTROL**	1-10 11-20	Male Female
2.	**II LOW DOSE**	21-30 31-40	Male Female
3.	**III MID DOSE**	41-50 51-60	Male Female
4.	**IV HIGH DOSE**	61-70 71-80	Male Female

The test item was administered for a period of 90 days. All animals in group I to IV were observed for 90 days.

Observations:

The observations included but were not restricted to changes in skin and the eyes and mucous membranes and in the respiratory, circulatory, central and autonomous nervous systems and behavior.

Clinical signs of toxicity:

All the rats were observed at least two times daily with the purpose of recording any symptoms of ill- health or behavioral changes and clinical signs of toxicity daily for 90 days for animals in group I to IV.

Food intake:

A measured amount of feed was kept in the cages and then after 24 hrs the left out amount of feed was measured to calculate the amount of food consumed by the rats.

Water intake:

Water intake was observed by visual observation during the Study. In addition, the water consumption in each cage was observed daily for a period of 90 days.

Bodyweight:

The body weight of rats was recorded one week before the start of treatment, and during the course of the treatment on day one and weekly once. The mean weights for all groups and sexes were calculated from the individual weights.

Pre-terminal deaths:

All rats were observed twice daily for any pre terminal deaths.

Blood Collection:

Blood was collected through abdominal aorta from all the animals of four groups on 90th day. The blood was collected in tubes containing as an anticoagulant (Heparin/EDTA). Animals were fasted overnight prior to the blood collection.

Laboratory studies:

During the 4th week of treatment, blood were withdrawn from the orbital sinus of animals from each group, under ketamine anesthesia .The blood samples are used to evaluate Hematological parameters like RBC, WBC, and platelets etc….. The collected blood samples also centrifuged 10000 rpm in 10 minutes to separate the serum. The separated serum used to evaluate biochemical parameters like SGOT, SGPT, ALP and BILIRUBIN etc……...

Hematology

The following hematological parameters were analysed (Autoanalyser) Hb: Haemoglobin (g %), PCV: Packed Cell Volume, WBC : White Blood Corpuscles (x103/cmm) , RBC : Red Blood Corpuscles (x106/cmm) ,Blood Platelet count (x103/cmm)

Differential WBC count:

Clinical Biochemistry:

The following clinical Bio parameters were analysed using Auto analyser. Total serum protein (g/dl) ,ALT/SGPT : Alanine amino transferase (U/L) ,AST/SGOT : Aspartate amino transferase (U/L) ,ALP : Alkaline serum phosphatase (U/L) ,CHL : Cholesterol (mg/dL) ,TGL : Triglyceride

Sacrifice and macroscopic examination

At the end of study period, the overnight fasted (water *ad libitum*) animals were anaesthetized with thiopentone sodium, blood samples were collected from retro-orbital sinus. After blood collection, the animals in group 1 to 4 were sacrificed on 90th day.

Organ weights:

After the macroscopic examination the following organs were weighed after separating the superficial fat: Brain, Heart, Spleen Kidneys, sex organs, Liver and Lungs.

Histopathology:

The target organs from control and drug treated animals were preserved in 10 % buffered neutral formalin for histopathological examination. Control and highest dose animals will be initially subjected to histopathological investigation. If any abnormality were found in the high dose group and then the low and mid group will be examined. All deviations from normal histology were recorded and compared with corresponding controls.

Statistical analysis:

Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett‟ s. $P< 0.05$ considered as significant by comparing treated group with control group.

CLINICAL STUDY:

Clinical trial Approval & Registration:

The Clinical trial was approved by the Institutional Ethics Committee (IEC) of National Institute of Siddha, Chennai 47 (NIS/IEC/2016/11-15/14.10.16) and further registered in Clinical Trial Registry of India (CTRI/2018/04/013023).

Study Centre:

Clinical study was conducted at AyothidossPandither Siddha Hospital, National Institute of Siddha (NIS), Tambaram Sanatorium, Chennai - 47. Necessary permission was obtained from the Administrative head to conduct the study.

SUBJECT SELECTION:

Patients reporting with symptoms of inclusion criteria would be subjected to screening test and documentation.

INCLUSION CRITERIA:

- Age : 30-65 years
- Sex : Both male and female
- Patient includes diabetic ulcer.
- With or without Pain, Itching, Edema, Fibrinous exudates in the lesions
- Hyper pigmentation
- Inflammation & Induration
- Willing to give specimen of blood for the investigation.
- Willing to take photograph.
- Willing to participate in trial and signing consent by fulfilling the condition of Proforma.

EXCLUSION CRITERIA:

- Extensive and localized Gangrene require amputation
- Osteo Myelitis
- Deep ulceration with bone, joint involvement
- Varicose ulcer
- Hansen’s disease
- Tuberculous ulcer
- Any other systemic illness.

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of any serious adverse effect during drug trial.
- Poor patient compliance & defaulters
- Patient unwilling to continue the course of clinical study.
- Occurrence of any other systemic illness.

TESTS AND ASSESMENTS:

1. Clinical assessment
2. Siddha system assessment
3. Routine investigations

CLINICAL ASSESMENT:

- Presence of ulcers
- Delay wound healing process
- With or without Pain, Itching, Edema, Fibrinous exudates in the lesions
- Hyper pigmentation
- Inflammation and Induration

INVESTIGATIONS BASED ON SIDDHA SYSTEM:

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram
    - Neerkkuri:
    - Neikkuri:

1. **INVESTIGATION:**

BLOOD

- Hb
- Total WBC Count
- DC
  - Polymorphs
  - Lymphocytes
  - Eosinophils
  - Monocytes
  - Basophils
- Total RBC count
- ESR ½ Hr: 1 Hr:
- Blood sugar

  Fasting: PP:
- Serum cholesterol

URINE

- Albumin
- Sugar(F) (PP)
- Deposits

RENAL FUNCTION TESTS

Blood Urea

Serum Creatinine

Uric acid

LIVER FUNCTION TESTS

Serum total bilirubin

Direct bilirubin

Indirect bilirubin

Serum Alkaline phosphatases

SGOT

SGPT

PRIMARY OUTCOME:

- The Outcome of the study was assessed by bates-jensen wound assessment tool etc.

BASED ON WOUND STATUS CONTINUUM

Wound Regeneration -13

Wound degenration – 60

GOOD **:** Complete healing of ulcer

MODERATE **:** Partial healing of ulcer

MILD **:** Slight reduction of ulcer

POOR **:** No reduction of ulcer

SECONDARY OUTCOME:

- To Assess Safety of the trial drug

DATA COLLECTION:

Required information was collected from each patient by using the following forms

FORMS:

FORM I	Screening and selection Proforma
FORM II	Clinical assessment Proforma
FORM III	Laboratory investigation Proforma
FORM IV	Drug compliance form
FORM V	Patient information sheet
FORM VI	Consent form
FORM VII	Withdrawal form/Pharmacovigilance
FORM VIII	Dietary Advice form

STUDY ENROLLMENT:

- Patients reporting at the OPD with clinical feature of chronic ulcer, oedema, Fibrinous exudates, present in the ulcer are chosen for enrollment based on the inclusion and exclusion criteria.

- The enrolled patients were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and getting consent in the informed Consent form (Form VI).

- Complete clinical history, complaints and duration, examination findings- all are recorded in the prescribed Performa's.

Screening Form- I would be filled up, Form –II and Form –III would be used for recording the patients, history, clinical examination of symptoms and signs and laboratory investigations respectively. If there is any abnormal laboratory reports obtained then excluded from this study. Patients would be advised to take the trial drug and appropriate dietary advice (Form VIII) would be given according to the patients, perfect understanding.

CONDUCT OF THE STUDY:

The day before the treatment Purgation were given with Agasthiyar Kuzhambu - 200mg in the early morning in empty stomach with Sangankuppi chaaru for balancing the deranged mukkutram. Then the trial drugs "***GANDHI MATHIRAI***" (Internal) and "***SAGALA RANANGALUKUM KALIMBU***" (External) were given for 48 days.

OPD patients are requested to visit the hospital every day. In each and every visit clinical assessment and prognosis were recorded every seven days once. For IPD patients the clinical assessment and prognosis were recorded daily.

Laboratory investigations were done before and after the trial. For IPD patients, who are not in a position to stay in the hospital for 48 days, are advised to attend the OPD for further follow-up.At the end of the trial, the patients are advised to visit the OPD for further 2 months for follow-up for any recurrence. Defaulters will not be allowed to continue and were withdrawn from the study with fresh case being inducted.

PHYSICO-CHEMICAL ANALYSIS RESULTS

S.NO	PARAMETERS	RESULTS
1.	Description	Solid state
	Colour	Black
	Odour	Mild characteristic odour
2.	Weight variations	Average weight of 0.0346 which is under the category of less than 80 mg
3.	Disintergration time	5-8 min

TEST FOR ACID FREE RADICLES:

S.NO	PROCEDURE	RESULTS
1.	Test for sulphate	+
2.	Test for chloride	-
3.	Test for phosphate	+
4.	Test for carbonate	+
5.	Test for nitrate	-
6.	Test for sulphide	-
7.	Test for fluride and oxalate	-
8.	Test for borate	-

Inference Bio-chemical analysis for acid radicals reveals that *Gandhi mathirai* contains sulphate, phosphate, and carbonate.

TEST FOR BASIC RADICLES:

S.NO	PROCEDURE	RESULTS
1.	Test for lead	-
2.	Test for copper	-
3.	Test for alumium	+
4.	Test for iron	+
5.	Test for zinc	-
6.	Test for calcium	-
7.	Test for magnesium	-

8.	Test for ammonium	-
9.	Test for pottasium	-
10.	Test for sodium	-
11.	Test for mercury	-
12.	Test for arsenic	-

Inference Bio-chemical analysis for basic radicals reveals that *Gandhi mathirai* contains aluminum and Iron.

MISCELLANEOUS:

S.NO	PROCEDURE	RESULTS
1.	Test for starch	-
2.	Test for reducing sugar	-
3.	Test for alkaloids	+
4.	Test for tannic acid	+
5.	Test for unsaturatedcompound	-
6.	Test for the type of compound Oxy quinole epinephrine and pyro catechol	+

Inference Bio-chemical analysis for miscellaneous reveals that *Gandhi mathirai* contains alkaloids, tannic acid and oxy quinole epinephrine.

PHYTO CHEMICAL ANALYSIS:

S.NO	PROCEDURE	RESULTS
1.	Alkaloid	-
2.	Flavonoids	+
3.	Glycosides	+
4.	Steroids	-
5.	Triterpenoids	-
6.	Coumarin	+
7.	Phenols	+
8.	Tannin	+

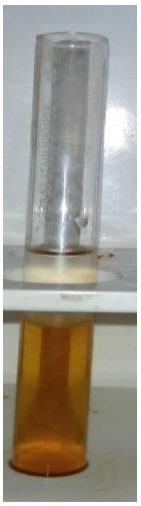
9.	Protein	-
10.	Saponins	+
11.	Sugar	-
12.	Anthocyanin	-
13.	Betacyanin	-

RESULTS

Test for Alkaloids

Test for Flavonoids

Test for Glycosides

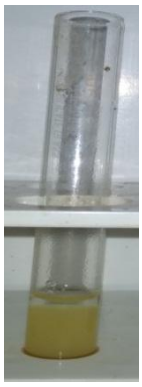


Test for Steroids

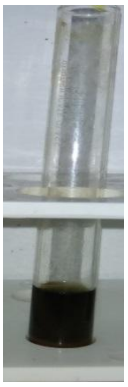
Test for Triterpenoids

Test for Coumarins

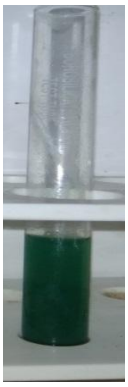
Test for Phenols



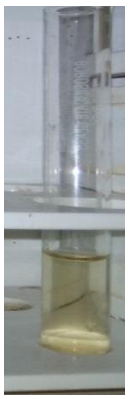
Test for Tanins



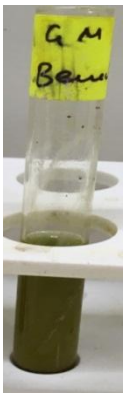
Test for Protein



Test for Saponins



Test for Carbohydrates



Test for Anthocyanins/ Beta cyanins

Inference: phyotchemical analysis reveals that *Gandhi mathirai* contains flavonoids, tannin, glycosides,coumarin, phenols,saponins.

HEAVY METAL ANALYSIS

HEAVY METAL	SPECIFICATION AS PER AYUSH/WHO/FDA	OBSERVED RESULT
Lead	10ppm	0.93ppm
Cadmium	0.3ppm	9.4
Arsenic	3.0ppm	1.344
Mercury	1ppm	BDL

Inference: The heavy metals such as cadmium, arsenic and mercury are not detected and the presence of lead is within the permissible limit.

TEST FOR AFLATOXINS AND PESTICIDE RESIDUES

S.NO	TEST	OBSERVED RESULT
1.	Aflatoxin B1	ND
2.	Aflatoxin B2	ND
3.	Aflatoxin G1	ND
4.	Aflatoxin G2	ND
5.	Organophosphorus	ND
6.	Organochloride	ND
7.	Synthetic pyrethroids	ND

TEST FOR BACTERIAL AND FUNGAL COUNT

TEST	SPECIFICATION AS PER AYUSH/WHO/FDA	OBSERVED RESULT
Total bacterial count	NMT 105 CFU/g	34,000CFU/g
Total fungal count	NMT 103 CFU/g	< 10 CFU/g
E.coli	Ab/ g	Ab/ g
Salmonella	Ab / g	Ab/ g
Pseudomonas aeruginosa	Ab/ g	Ab/ g
Staphyloccusaureus	Ab / g	Ab/ g

Inference: The bacterial and fungal loads are within the prescribed limits. The above results suggest that the prepared drug *Gandhi mathirai* is standard quality.

THIN LAYER CHROMATOGRAPHY CONDITIONS

S.NO	MOBILE PHASE	RF VALUE	NO OF COMPOUNDS	DETECTION
1.	Toluene: Ethyl Acetate: Acetic(1:5:1:0:5)Acid: Acetone()	0.06 and 0.93	6	254nm

TLC PROFILE OF GM (PHOTO DOCUMENTATION)

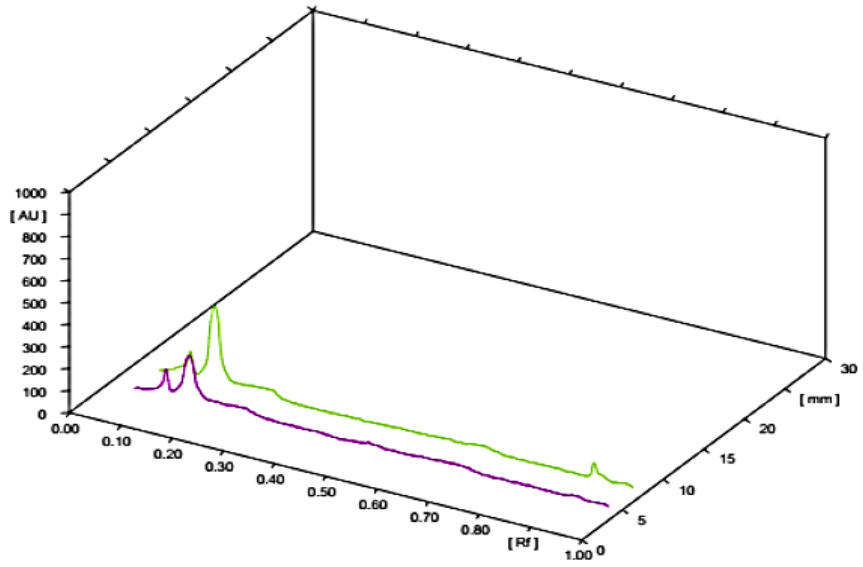
TLC Analysis at 254 nm

TLC plate visulization at visible range

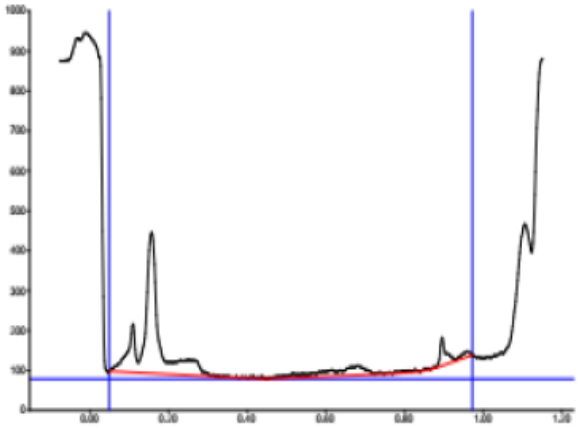
TLC Analysis at 366 nm

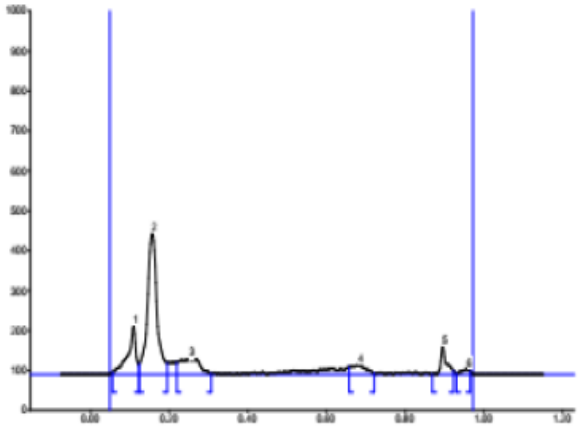
TLC after derivatization with 10% sulfuric acid

Track at All Wavelength



HPTLC finger printing of Sample GM





Peak Table

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.06	6.1	0.11	121.6	19.60	0.12	24.9	1876.5	16.15
2	0.12	25.6	0.16	352.2	56.80	0.20	28.9	6520.7	56.11
3	0.22	30.3	0.25	38.6	6.23	0.31	2.9	1553.0	13.36
4	0.66	18.4	0.68	24.1	3.89	0.72	3.6	695.4	5.98
5	0.87	0.6	0.90	70.0	11.29	0.92	9.7	759.5	6.54
6	0.93	2.2	0.96	13.5	2.18	0.97	8.3	215.2	1.85

RESULTS

HPTLC finger printing analysis of the sample GM reveals the presence of three prominent peaks corresponds to presence of six versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.06 to 0.93. Further the peak 2 occupies the major percentage of area of 56.11 % which denotes the abundant existence of such compound. Followed by this peak 1 and 2 occupies the percentage area of 16.15 and 13.36%.

PESTICIDE RESIDUES

Test Result Analysis of the Sample GM

Pesticide Residue	**Sample GM**	**AYUSH Limit (mg/kg)**
I. Organo Chlorine Pesticides		
Alpha BHC	BQL	0.1mg/kg
Beta BHC	BQL	0.1mg/kg
Gamma BHC	BQL	0.1mg/kg
Delta BHC	BQL	0.1mg/kg
DDT	BQL	1mg/kg
Endosulphan	BQL	3mg/kg
II.Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III.Pyrethroid Cypermethrin	BQL	1mg/k

BQL- Below quantification Limit

Result:

The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus and pyrethroids in the sample GM. It further shows the above mentioned residues were not been detected in the sample GM provided for analysis.

TOXICITY STUDY

Acutetoxicity

Gandhi mathirai was administered single time at the dose of 2gms/kg to rats and observed for consecutive 14 days after administration. According to the OECD guideline 423 when there is information in support of non-toxicity or low and immortality nature of the test substance, then the limit test at the dose level 2 gms/kg body weights (highest starting dose level) was conducted. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded. No mortality was observed during the total period of the study. Data obtained in this study indicated no significance physical and behavioural signs of any toxicity due to administration of **Gandhi mathirai** at the dose of 2gms/kg to rats. At the 14th day, all animals were observed for functional and behavioural examination. In functional and behavioural examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, involuntary movement, (Clonic and Tonic), Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities (Reactivity and Handling), Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioural examination was normal in all groups. Food consumption of all treated animals was found normal as compared to control group. The results of functional and behavioural examination were elicited in table below.

CLINICAL OBSERVATION OF CONTROL AND *GANDHI MATHIRAI* TREATED EXPERIMENTALANIMALS IN ACUTE TOXICITY STUDY

OBSERVATION		**SIGNS**	**OBSERVATION**	**SIGNS**
Lethality		X	Stereotypies(chewing)	X
Convulsion		X	Stereotypies (Head movements)	X
Tremor		X	Head twitches	X
Straub tail		X	Scratching	X
Sedation	#1	X	Respiration	X
	#2	X	Aggressiveness	X
	#3	X	Fear	X

Excitation	#1	X	Reactivity to touch	X
	#2	X	Muscle tone	X
	#3	X	Loss of rightingReflex	X
Abnormal gait(rolling)		X	Ptosis	X
Abnormal gait(tip toe)		X	Exophthalmos	X
Jumps		X	Loss of grasping	X
Motor coordination		X	Akinesia	X
Loss of balance		X	Catalepsy	X
Fore paw treading		X	Loss of traction	X
Writhes		X	Loss of corneal reflex	X
Piloerection		X	Analgesia	X
Salivation		X	Defecation	X
Lacrimation		X	Others	X

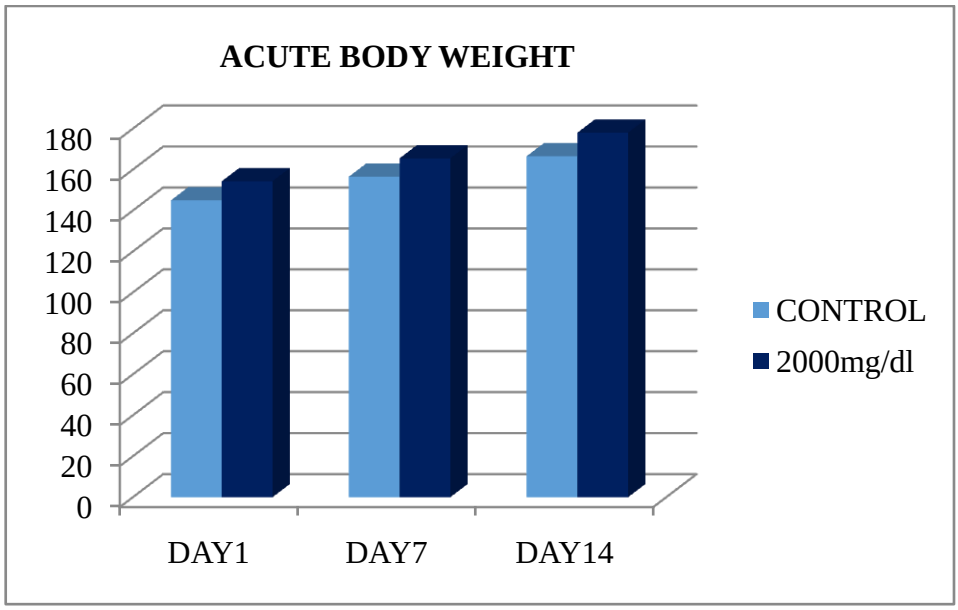
Others X X – no sign / √ - Present; Values are expressed as mean ± SD (n=3)

Body weight at weekly interval was measured to find out the effect of **Gandhi mathirai** on the growth rate. No significant body weight changes were observed between control and treatment group. There were no treatment related mortality in both control and treatment groups throughout the experimental period No pathological (gross) changes were observed in the experimental animals

EFFECT OF *GANDHI MATHIRAI* ON BODY WEIGHT OF WISTAR RATS IN ACUTE TOXICITYSTUDY

TREATMENT	Body weight (mean±SD)		
	Day 1	Day 7	Day 14
Control	145±0.58	156.5±0.35	166.5±0.58
GM (2000mg/kg)	154.3±0.81	165.5±0.65	178±0.32

Values are expressed as mean ±SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett‟ s. *P*< 0.05 considered as significant by comparing treated group with control group using Graph Pad 3.



Effect of GM on Body weight in WA Rats

GROSS PATHOLOGY OBSERVATIONS OF CONTROL AND *GANDHI MATHIRAI* TREATED EXPERIMENTAL ANIMALS

ORGANS	OBSERVATION
Brain	No abnormal lesion observed
Eyes	No abnormal lesion observed
Lymph node	No abnormal lesion observed
Trachea	No abnormal lesion observed
Oesophagus	No abnormal lesion observed
Lungs	No abnormal lesion observed
Heart	No abnormal lesion observed
Brain	No abnormal lesion observed
Liver	No abnormal lesion observed
Stomach	No abnormal lesion observed
Duodenum	No abnormal lesion observed
Small and large intestine	No abnormal lesion observed
Kidney	No abnormal lesion observed
Spleen	No abnormal lesion observed
Sex organs	No abnormal lesion observed
Pancreas	No abnormal lesion observed

REPEATED DOSE 90 DAYS ORAL TOXICITY STUDY:

Clinical Signs :

No abnormal home cage activities, behavioral responses or neurological symptoms were observed before and after the exposure of GM. All animals in this study were free of toxic clinical signs throughout the dosing period of 90days

Mortality:

Since examination of clinical signs plays main role in toxicological testing, mortality and morbidity were recorded two times a day throughout the study. All animals in control and in all the treated dose groups survived during the dosing period of 90 days

Body weight:

Results of body weight determination of animals from control and different dose groups exhibited comparable body weight gain (throughout the dosing period of 90 days

Food and water consumption:

Feed and water consumption of GM treated groups were found to be in significant in both the sexes when compared to control. The faecal/urinary excretion patterns were also found to be normal in GM administered rats in comparison to the vehicle treated rats.

CLINICAL OBSERVATION OF CONTROL AND GM TREATED EXPERIMENTAL ANIMALS IN- REPEATED DOSE 90DAYS ORAL TOXICITY STUDY

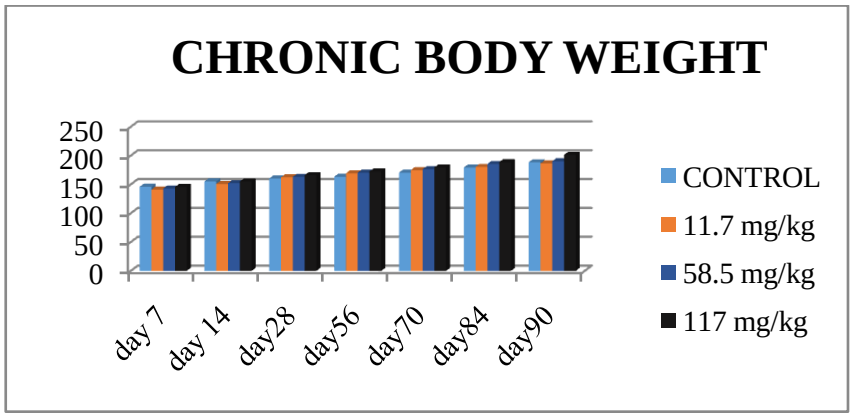
OBSERVATION		**SIGNS**	**OBSERVATION**	**SIGNS**
Lethality		X	Stereotypies(chewing)	X
Convulsion		X	Stereotypies (Head movements)	X
Tremor		X	Head twitches	X
Straub tail		X	Scratching	X
Sedation	#1	X	Respiration	X
	#2	X	Aggressiveness	X
	#3	X	Fear	X
Excitation	#1	X	Reactivity to touch	X
	#2	X	Muscle tone	X
	#3	X	Loss of rightingReflex	X
Abnormal gait(rolling)		X	Ptosis	X
Abnormal gait(tip toe)		X	Exophthalmos	X
Jumps		X	Loss of grasping	X
Motor coordination		X	Akinesia	X
Loss of balance		X	Catalepsy	X
Fore paw treading		X	Loss of traction	X
Writhes		X	Loss of corneal reflex	X
Piloerection		X	Analgesia	X
Salivation		X	Defecation	X
Lacrimation		X	Others	X

Others X X – no sign / √ - Present; Values are expressed as mean ± SD (n=3)

EFFECT OF *GANDHI MATHIRAI* ON BODY WEIGHT OF EXPERIMENTAL WISTAR RATS IN 90 DAYS REPEATED ORAL TOXICITY STUDY

Treat-ment	1st Day	14th day	28th day	56th day	70th Day	84th day	90th
Control	145.90± 0.6	155±2.0	160.4± 036	163.20± 0.85	170.40± 0.98	179.3± 0.96	188.3± 0.98
11.7 mg/dl	140±0.9	150.7±0.45	162.3±0.21	169.21±0.63	174.70± 0.74	180.30± 0.14	186.4± 0.54
58.5 mg/dl	142±0.34	152±0.45	163.1± 0.35	170.31± 0.65	176.3±0.69	185.4± 0.36	190± 0.87
117 mg/dl	145±0.23	155±0.63	166± 0.69	172.4±86.2	179.50±0.86	188.6± 0.87	200.10± 0.36

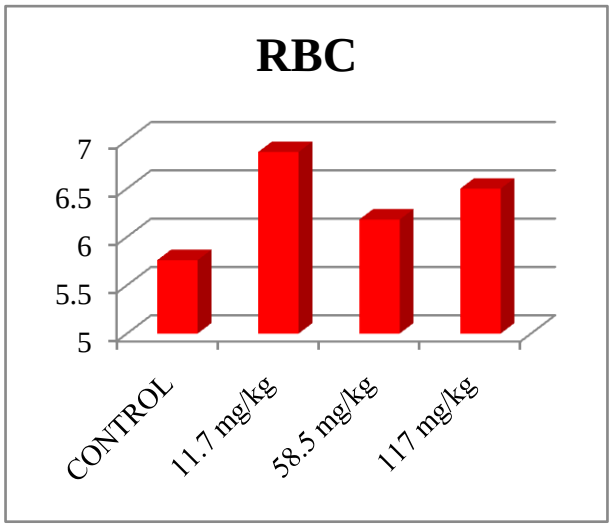
Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. *P*< 0.05 considered as significant by comparing treated group with control group using Graph Pad Prism 3.0.

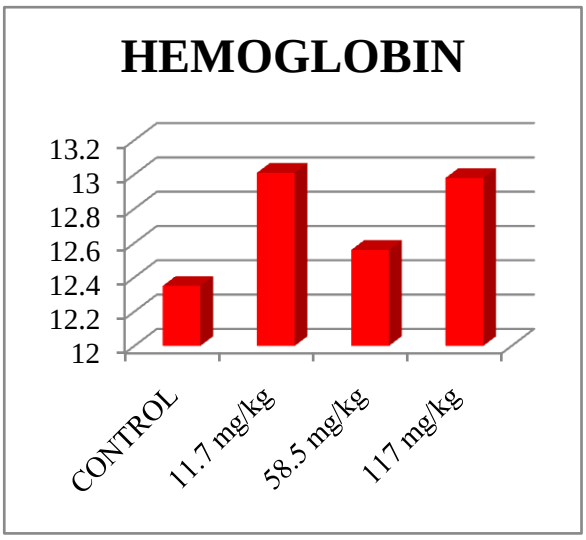


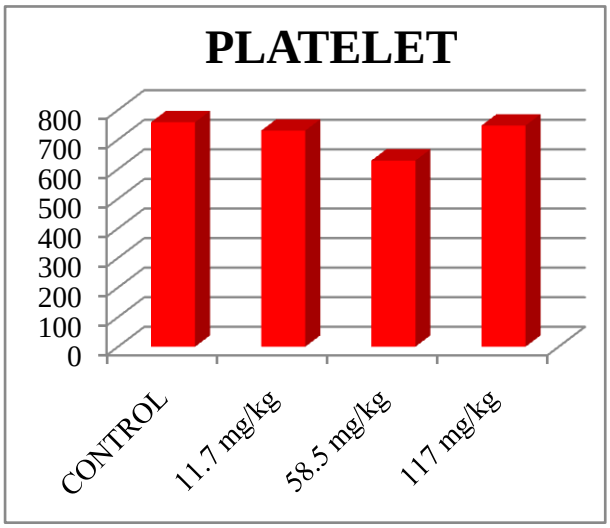
Effect of GM on Body weight in WA Rats

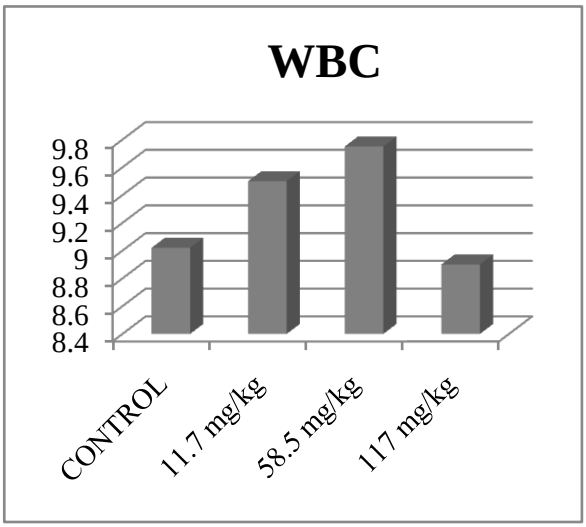
HEMATOLOGICAL INVESTIGATIONS

The haemopoietic system serves as vital goal for toxic chemicals and is a susceptible index for pathological conditions both in humans and animals. The results of hematological investigations conducted on day 90 does not revealed any significant changes in the values of various parameters observed when compared with those of respective controls .









EFFECT OF *GANDHI MATHIRAI* ON HEMATOLOGICAL PARAMETERS OF EXPERIMENTAL WISTAR RATS IN REPEATED DOSE 90DAYS ORAL TOXICITY STUDY

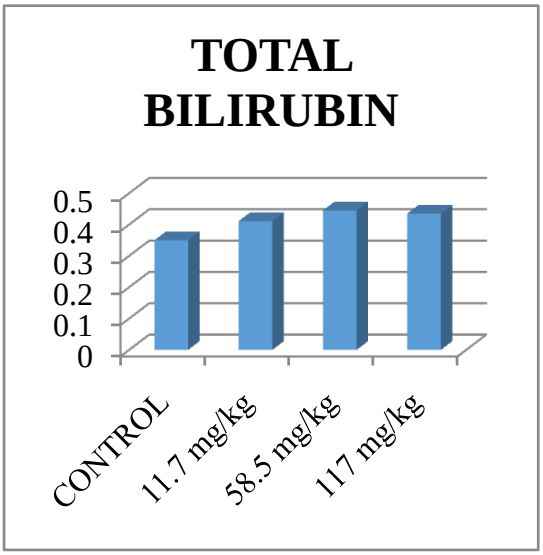
TREATMENT	RBC(106/uL)	WBC (103/uL	PLATELET 103/uL	HB mg/dl
Control	5.76 ± 0.512	9.02 ± 2.14	759 ± 75.7	12.35 ± 1.82
11.7mg/dl	6.885 ±0.81	9.5 ± 2.28	730.6 ± 1.27	13.0 ± 1.37
58.5mg/dl	6.81 ± 0.57	9.75 ± 2.21	629.4 ± 90.0	12.54± 1.59
117mg/dl	6.5 ± 1.010	8.27 ± 1.52	747.7 ± 23.2	12.98 ±1.26

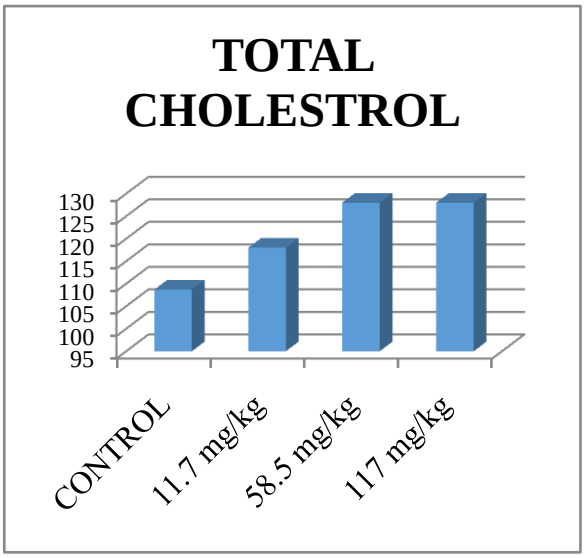
RBC: red blood corpuscles; Hb: hemoglobin; MCH: mean corpuscular hemoglobin; WBC: white blood cells PCV: packed cell volume. Values are expressed as mean ± SD.

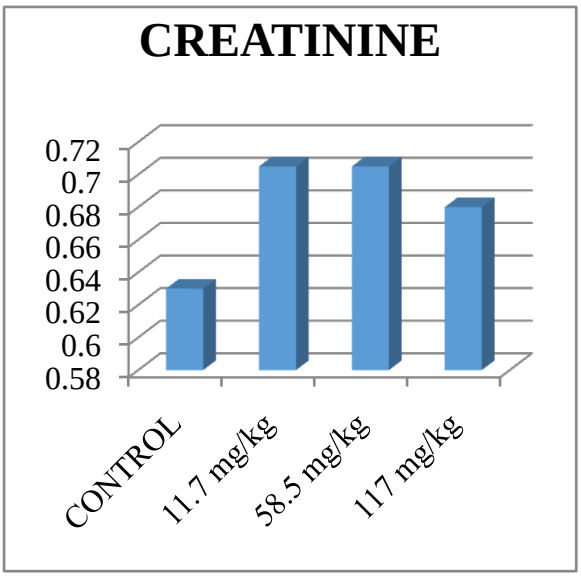
Statistical significance (p) calculated by one way ANOVA followed by dunnett" s. $P< 0.05$ considered as significant by comparing treated group with control group using Graph Pad Prism 3.0.

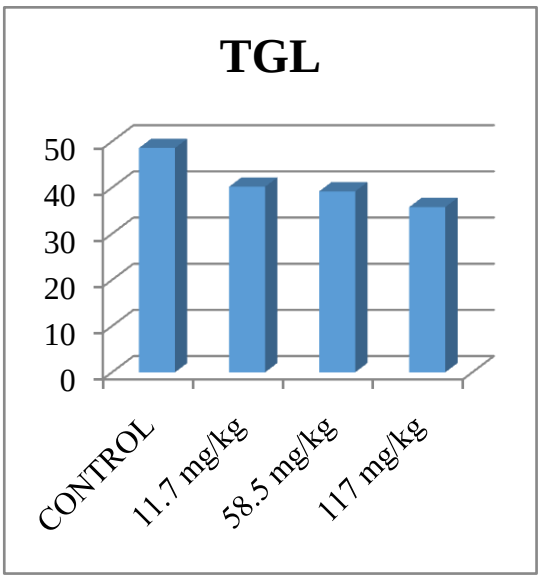
BIOCHEMICAL INVESTIGATIONS

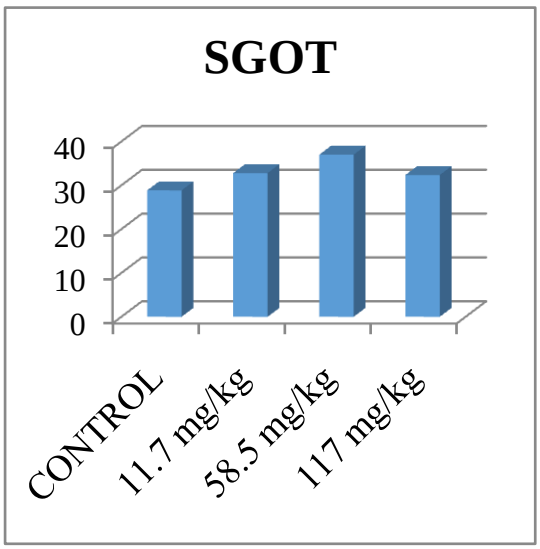
Clinical biochemistry and hematological data holds major role in determining the toxicity induced by drugs. Transaminases (SGPT and SGOT) are good indicator of liver function and biomarkers to calculate the possible toxicity of drugs. Any elevation pertaining to these enzymes specifies their out flow into the blood stream due to injure in liver parenchymal cells. Results of Biochemical investigations conducted on days 90 does not revealed significant changes in the values of hepatic serum enzymes studied when compared with those of respective control.

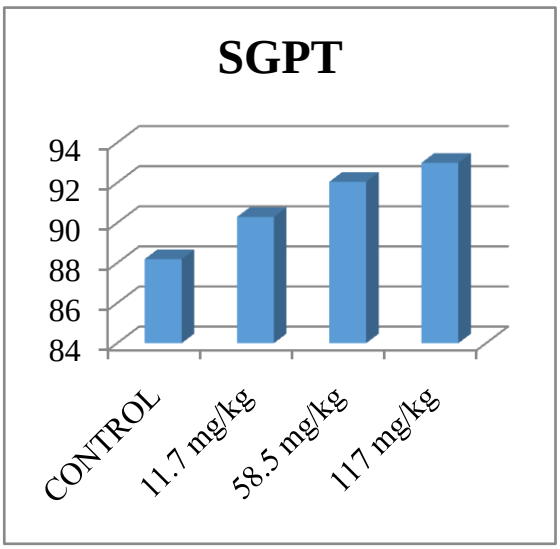

TOTAL BILIRUBIN
0.5
0.4
0.3
0.2
0.1
0
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg


TOTAL CHOLESTROL
130
125
120
115
110
105
100
95
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg


CREATININE
0.72
0.7
0.68
0.66
0.64
0.62
0.6
0.58
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg


TGL
50
40
30
20
10
0
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg


SGOT
40
30
20
10
0
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg


SGPT
94
92
90
88
86
84
CONTROL
11.7 mg/kg
58.5 mg/kg
117 mg/kg

EFFECT OF *GANDHI MATHIRAI* ON BIOCHEMICAL PARAMETERS OF EXPERIMENTAL WISTAR RATS IN REPEATED DOSE 90DAYS ORAL TOXICITY STUDY

Treatment	SGPT U/I	SGOT U/I	Total Bilirubin mg/dl	Total Cholestrol mg/dl	TGL mg/dl	Creatinine mg/dl
Control	88.5 ± 0.74	88.2 ±11.1	0.33 ±0.166	108.7 ±13.4	48.6 ± 4.86	0.68 ±0.218
11.7mg/dl	32.82 ± 8.88	90.3 ±20.5	0.515 ±0.36	118.2 ± 18.2	40.2 ±6.5	0.705 ±0.26
58.5mg/dl	32 ± 9.13	92.05 ±22.3	0.445 ±0.25	128.9 ±10	39.2 ±6.9	0.7 ±0.16
117mg/dl	32.35 ± 9.13	97 ±15.8	0.43 ±1.082	108.2 ±12.2	35.8 ±7.5	0.63 ±0.29

TGL: triglycerides, SGOT: Serum Glutamic oxaloacetic Transaminase, SGPT: serum glutamic pyruvic transaminase, ALP: Alkaline phosphatase. Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett‟s. *P*< 0.05 considered as significant by comparing treated group with control group using Graph Pad Prism 3.0.

HISTOPATHOLOGY:

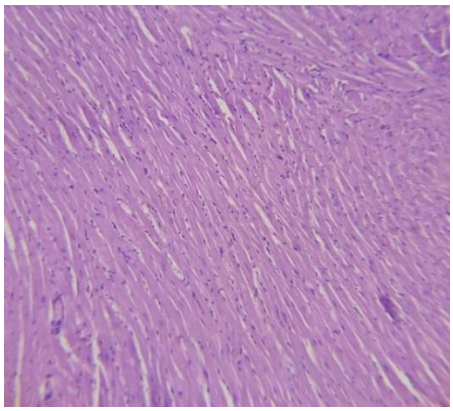
Histopathological studies give supportive evidence for biochemical and haematological observations. The histopathological examination carried out in the control and high dose animals treated with GM. In histopathological examination, revealed normal architecture in comparison with control and all treated group animals.

ORGANS	OBSERVATION
Brain	No abnormal lesion observed
Heart	No abnormal lesion observed
Liver	No abnormal lesion observed
Spleen	No abnormal lesion observed
Kidney	No abnormal lesion observed
Lung	No abnormal lesion is observed

EFFECT OF GM ON HISTOPATHOLOGICAL CHANGES IN RAT ORGANS REPEATED DOSE 90DAYS ORAL TOXICITY STUDY:

Control Male
Histopathology of Heart

Low Power Magnification 10X



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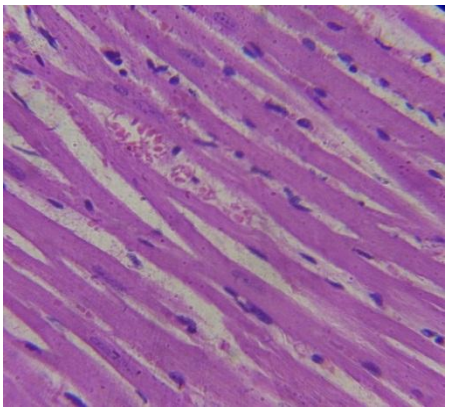
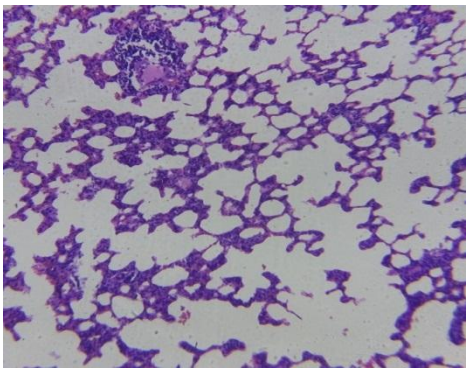


Histopathology of Lung

Low Power Magnification 10X



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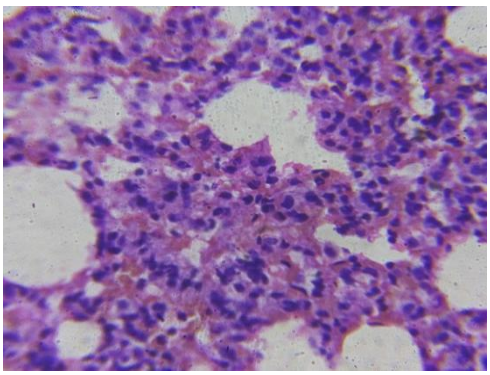

Histopathology of Liver

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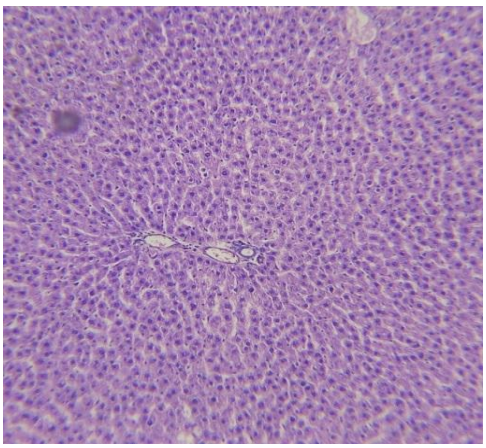

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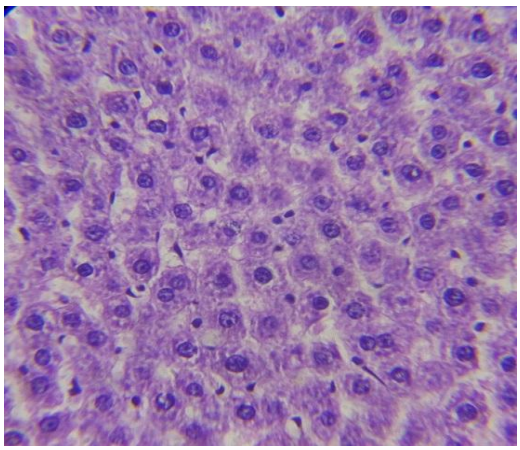

Histopathology of Kidney

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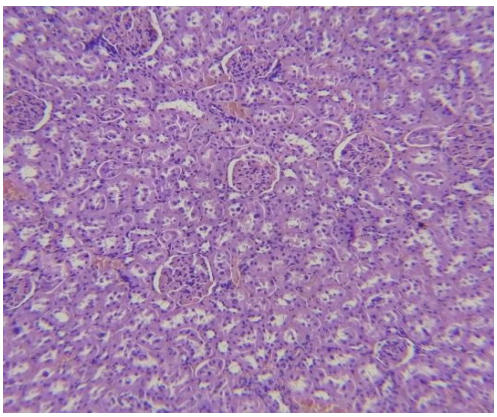

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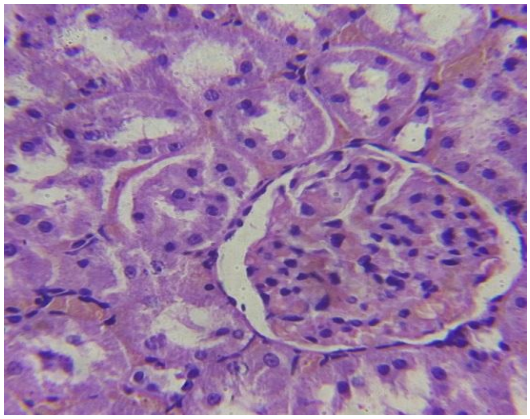

Histopathology of Spleen

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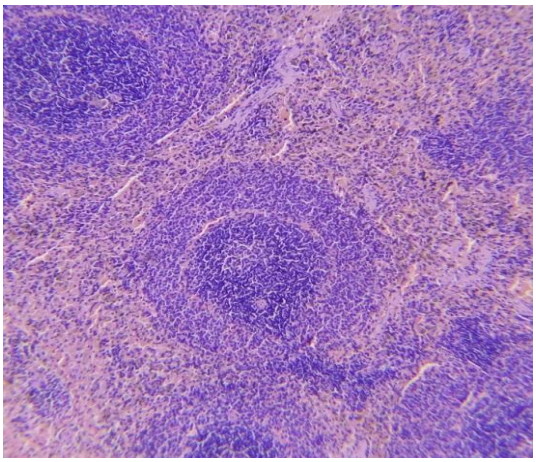

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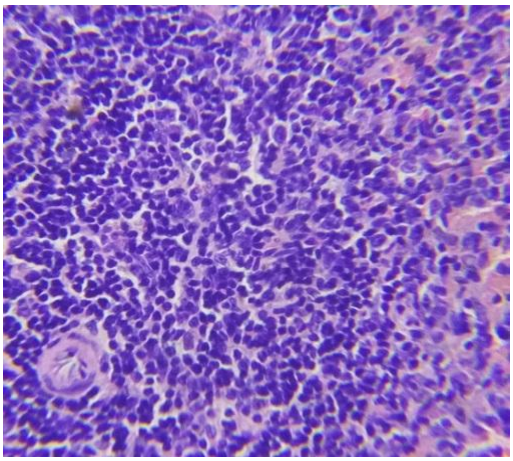

Histopathology of Testes

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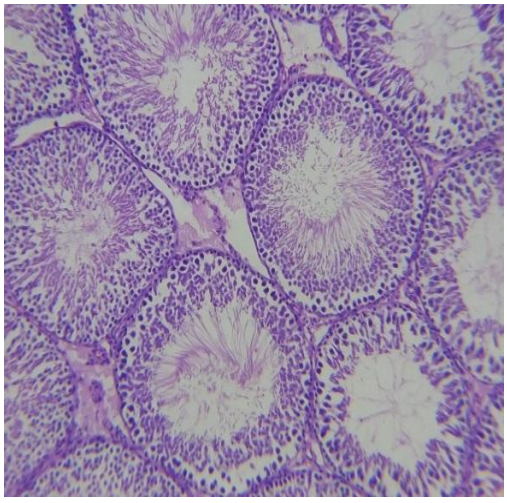

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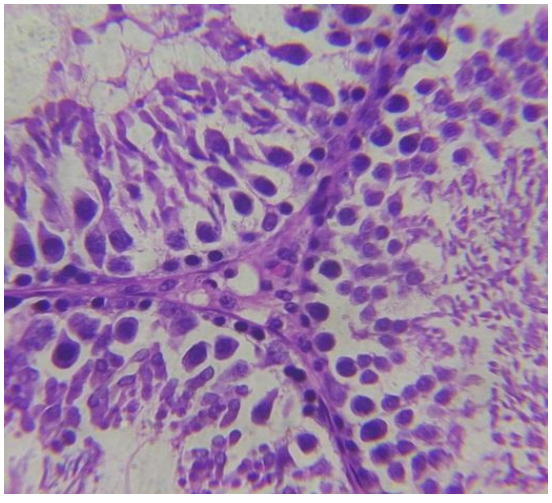
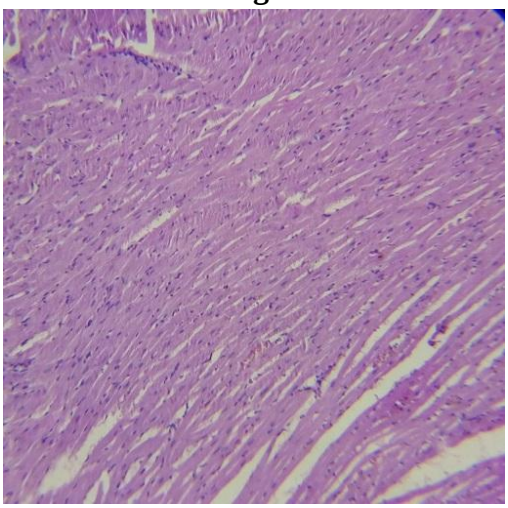


Results

Heart	No evidence of atherosclerosis and thrombosis No evidence of necrotic myocardium
Lung	Alveolar sac and septa appears normal with signs of degeneration
Liver	Appearance of terminal hepatic venules (central veins) to the portal tracts was normal No signs of nodular degeneration and cirrhosis
Kidney	Appearance of glomerular basement membrane was normal Lumen of vessels and bowman's space appears normal
Spleen	Presence of marginal at the interface of the red pulp with the PALS and follicles was observed Marginal sinus (MS) of the rat and its sinus lining cells appears normal
Testes	Presence of mature somatic cells project the perfect histomorphology of testicular cells were observed. Primary spermatocytes with large centered nucleus and dense chromatin were observed

Control Female
Histopathology of Heart

Low Power Magnification 10X



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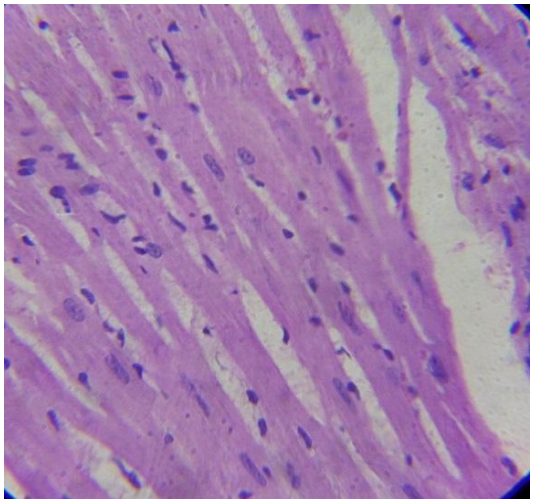
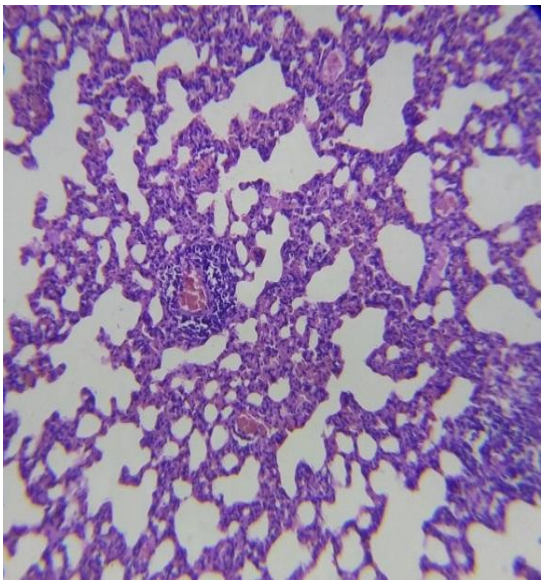


Histopathology of Lung

Low Power Magnification 10X



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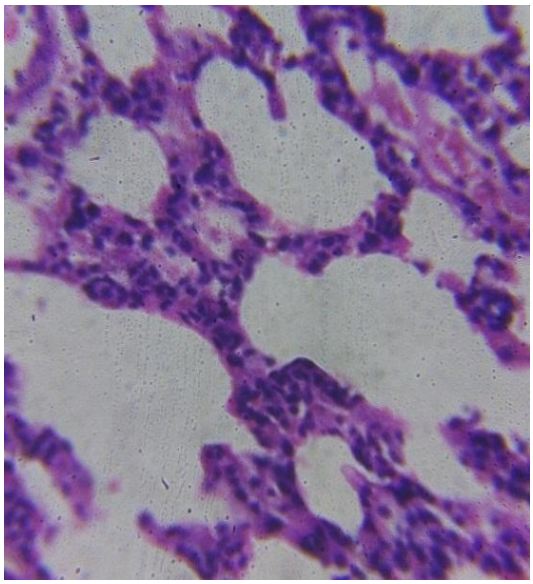
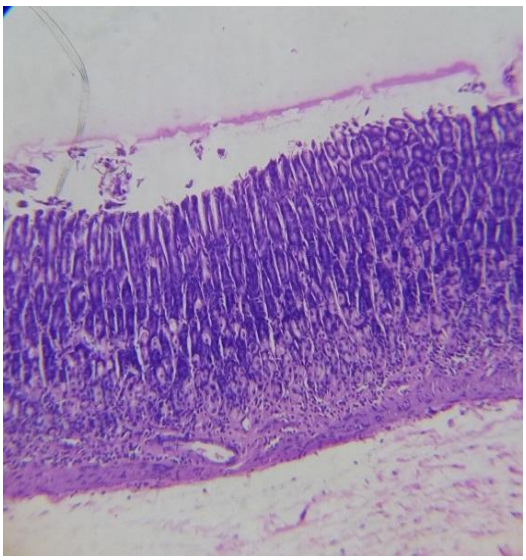


Histopathology of Stomach

Low Power Magnification 10X



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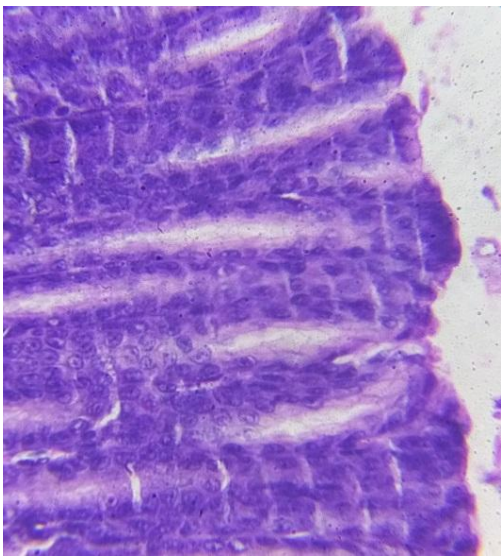

Histopathology of Liver

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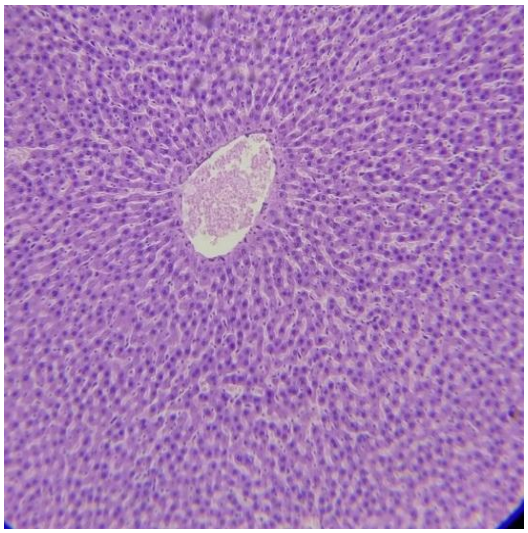

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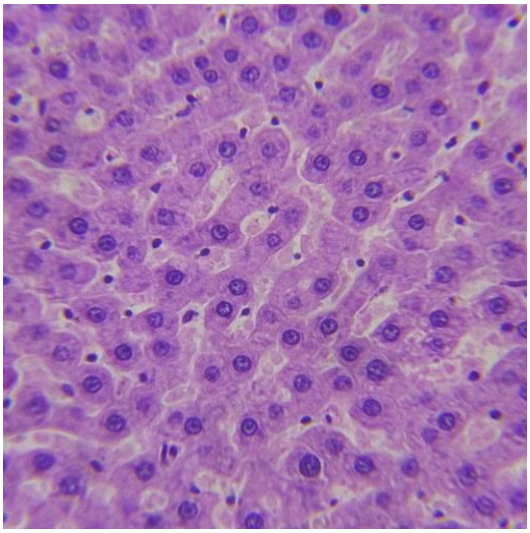

Histopathology of Kidney

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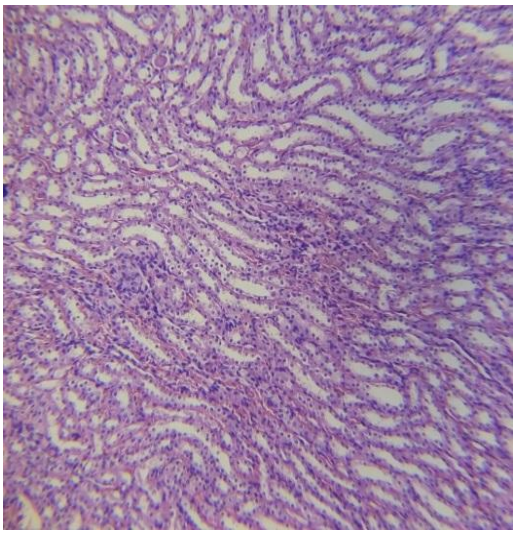

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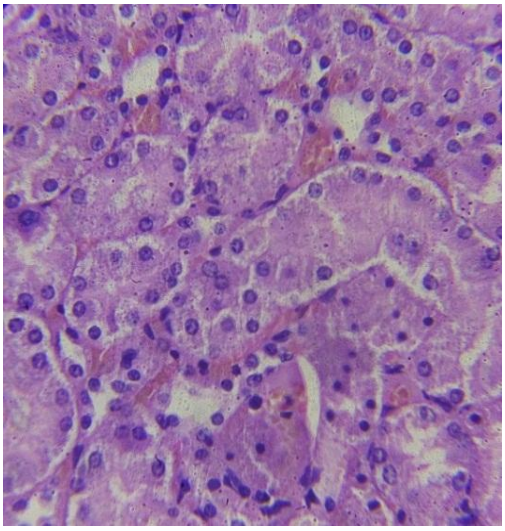

Histopathology of Spleen

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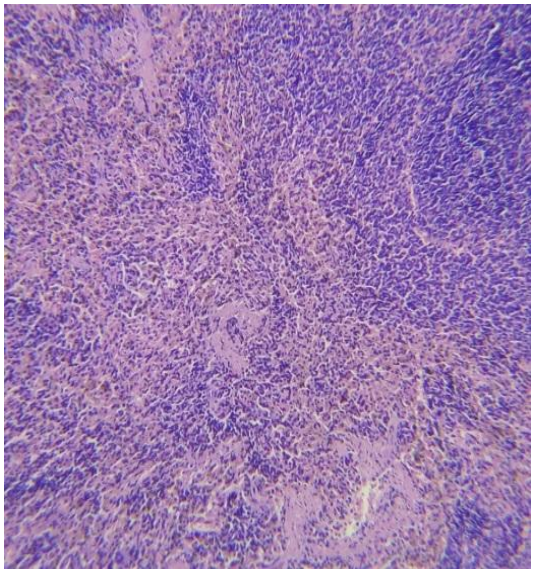

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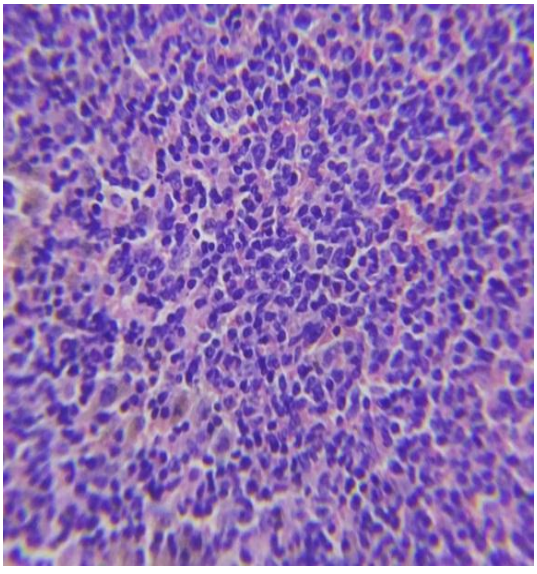
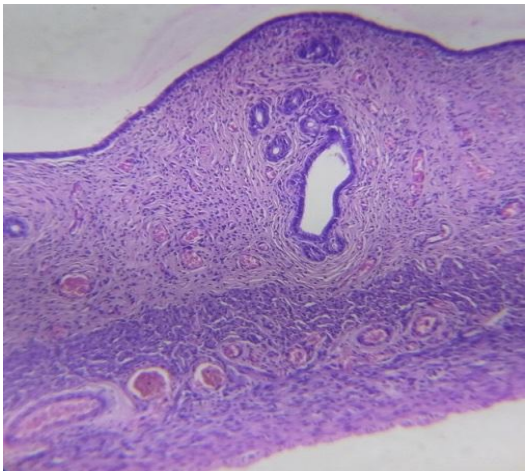


Histopathology of Uterus

Low Power Magnification 10X



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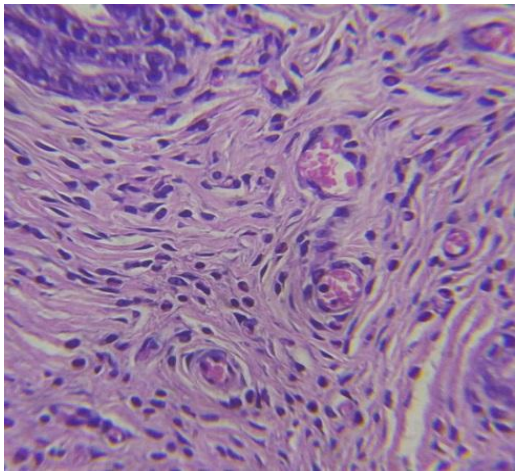
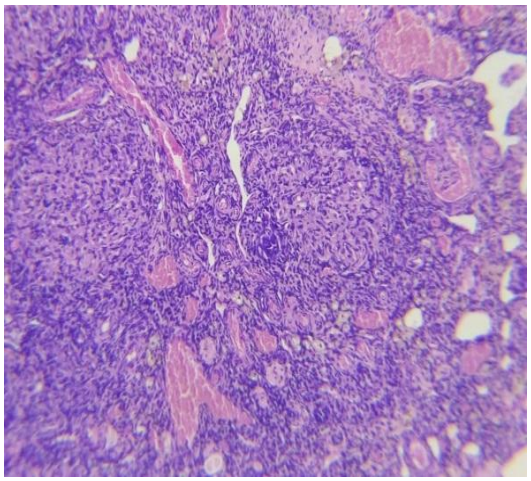


Histopathology of Ovary

Low Power Magnification 10X



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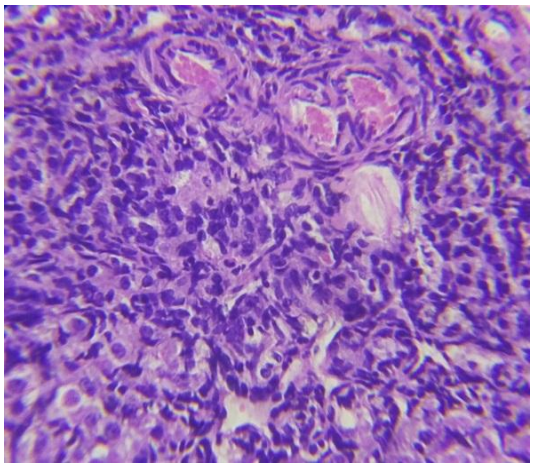


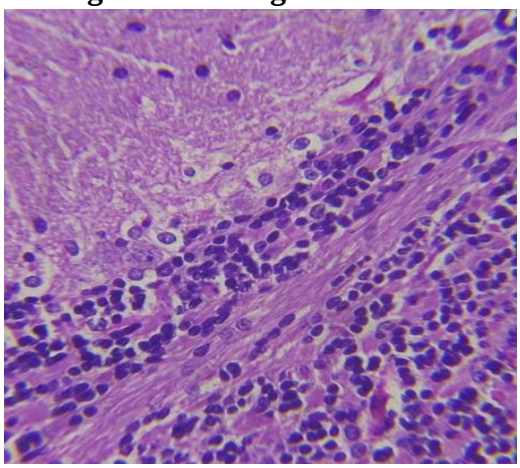
Results

Heart	Appearance of fibrils and cross striations are equidistant
Lung	Perivascular region appears normal, Alveolar septa and wall appeared widen and normal
Stomach	Regular histology of Inner circular muscle (ICM), gastric pit (GP), and muscularis mucosae (MM) were observed
Liver	Centrilobular zone appears normal with stable network of hepatocytes The walls of the lumen appears normal with no evidence of ischemic changes.
Spleen	Appearance of splenic sinuses, Splenic cord and endothelial orientation was normal
Uterus	Endometrial stroma; G, gland; M, myometrium; P, perimetrium; L, lumen exhibits normal histological aspect of endometrium and myometrium.
Ovary	Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality

HDMB- GM
Histopathology of Brain

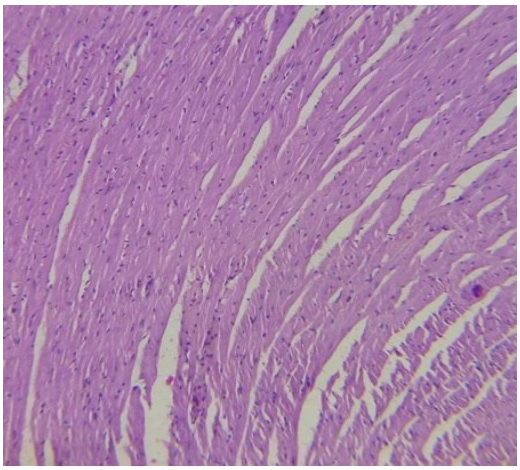
Low Power Magnification 10X

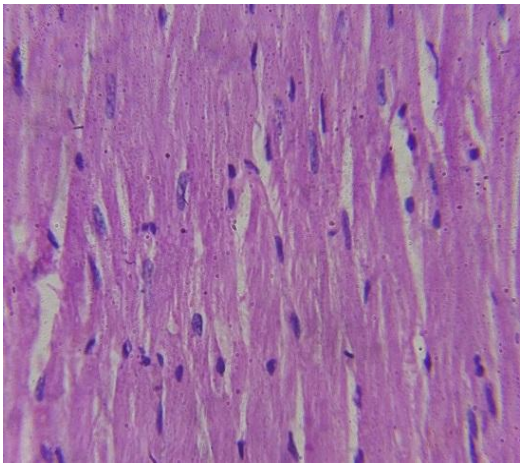
High Power Magnification 40X



Histopathology of Heart

Low Power Magnification 10XHigh Power Magnification 40X





Histopathology of Lung

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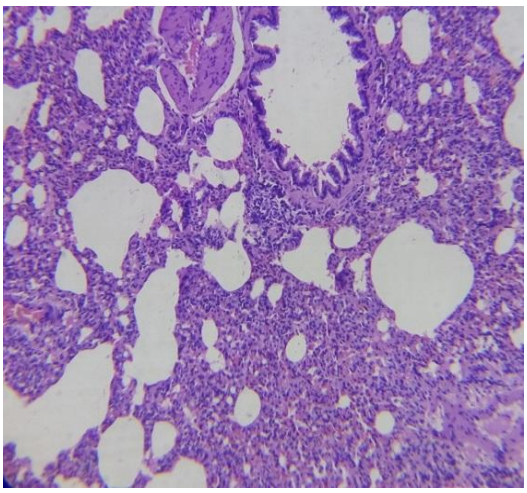

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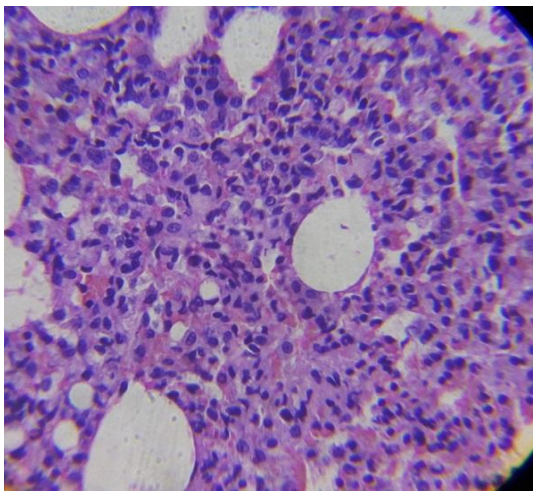
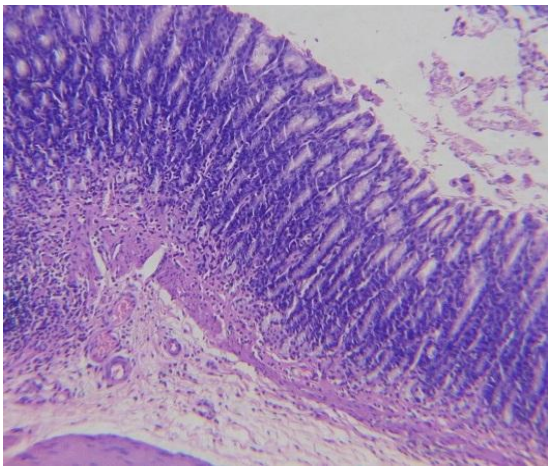


Histopathology of Stomach

Low Power Magnification 10X



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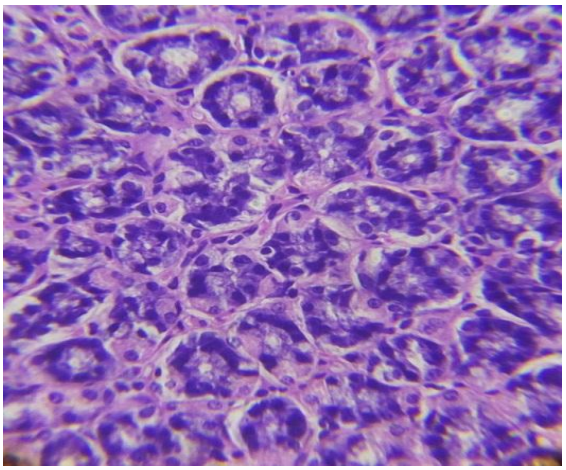

Histopathology of Liver

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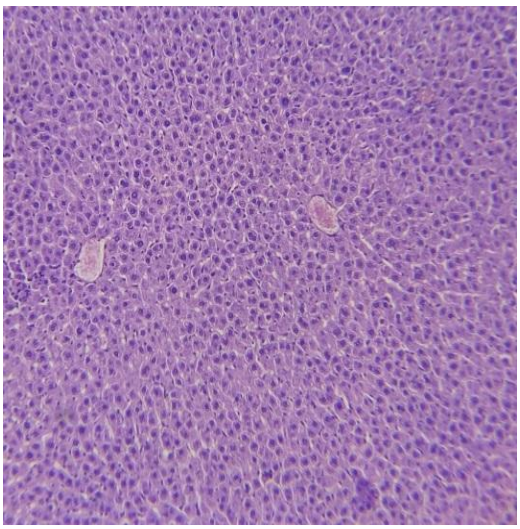

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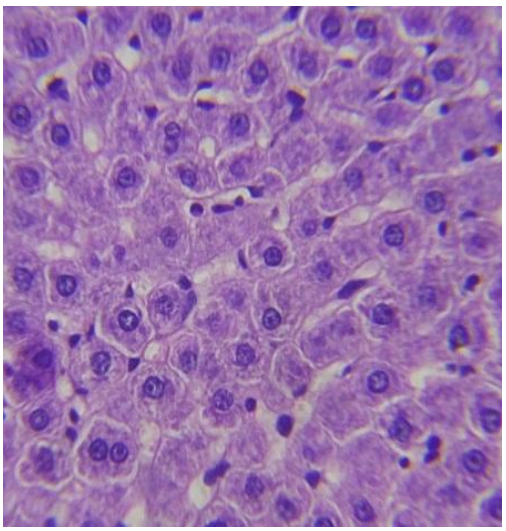
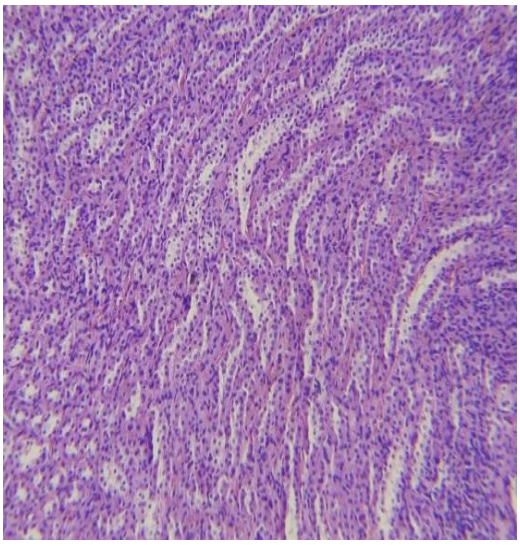


Histopathology of Kidney

Low Power Magnification 10X



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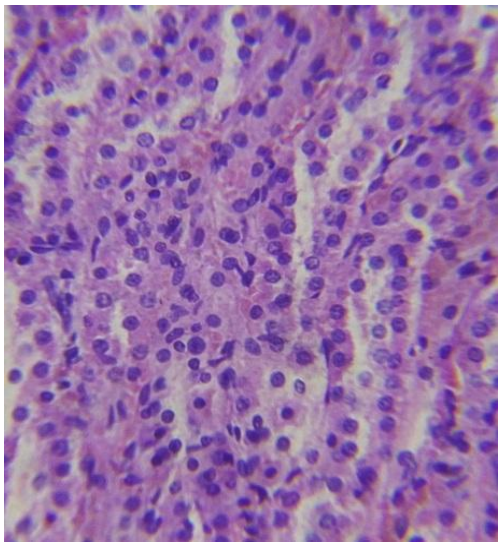
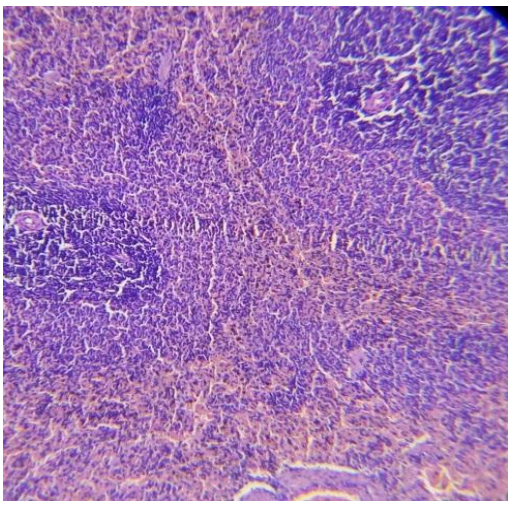


Histopathology of Spleen

Low Power Magnification 10X



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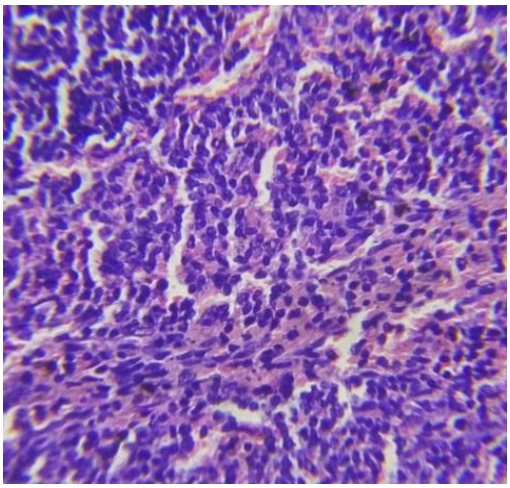
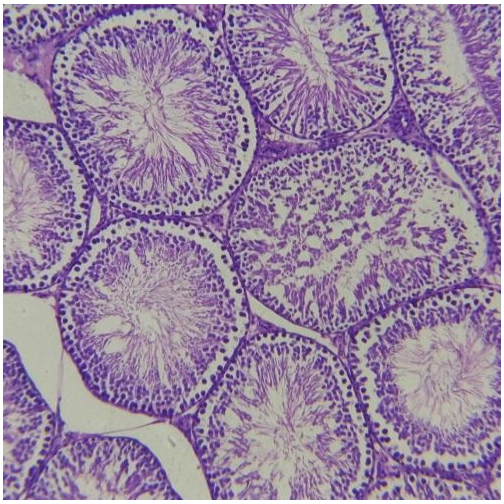


Histopathology of Testes

Low Power Magnification 10X



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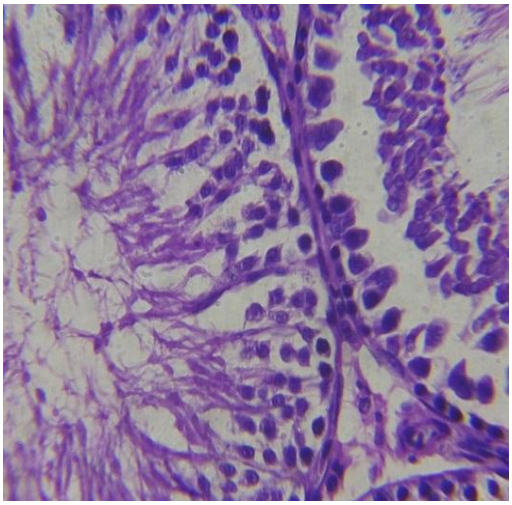


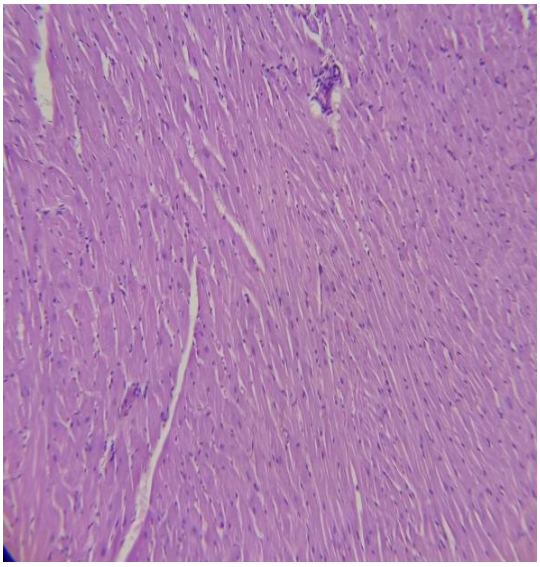
Results

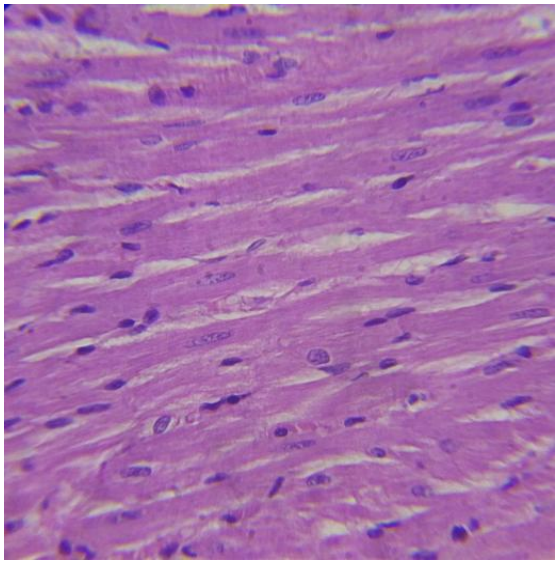
Brain	In cerebellum the molecular, purkinje and granular layers, appeared clear and distinct without any changes.
Heart	Fibres appears normal elongated and rod shaped
Lung	Respiratory and terminal bronchioles appears normal
Stomach	Normal gastric mucosa containing intact gastric gland cells, parietal cells which are spherical cell with deeply stained dark nucleus
Liver	The centrilobular hepatocytes appears normal with stained prominent cytoplasm
Kidney	Appearance of proximal and distal convolutes tubules was normal
Spleen	Appearance of splenic red pulp was normal
Testes	Section of testis of showing normal interstitial connective tissue and normal; proliferating highly divided germ cells with elongated sertoli cells

HDFH- GM

Histopathology of Heart

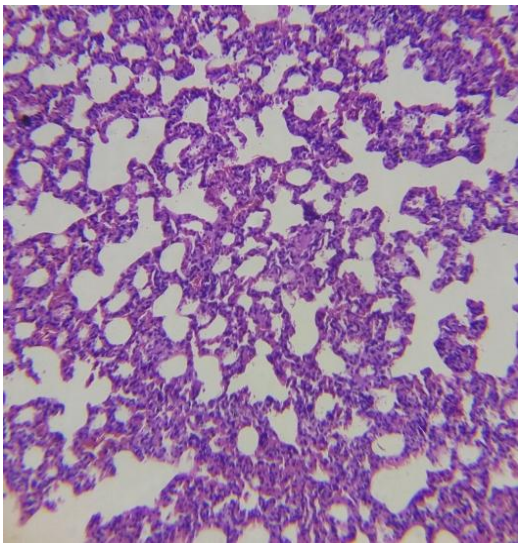
Low Power Magnification 10X **High Power Magnification 40X**

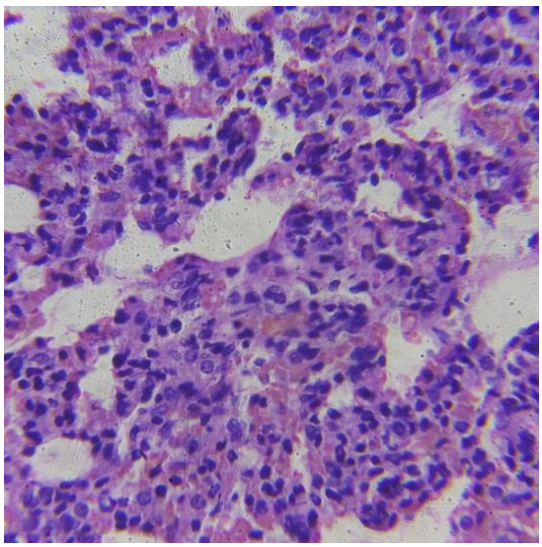




Histopathology of Lung

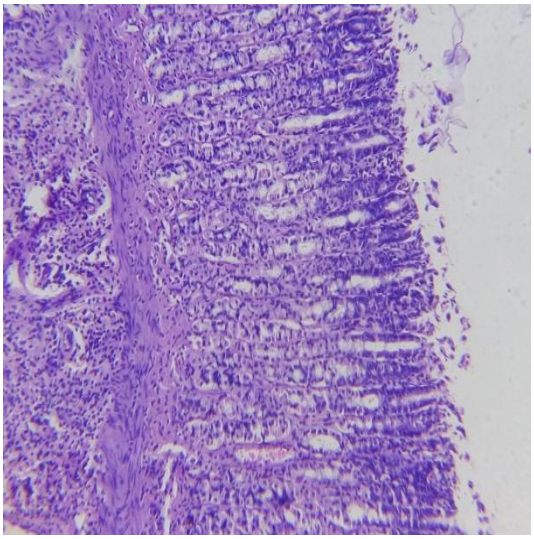
Low Power Magnification 10X **High Power Magnification 40X**

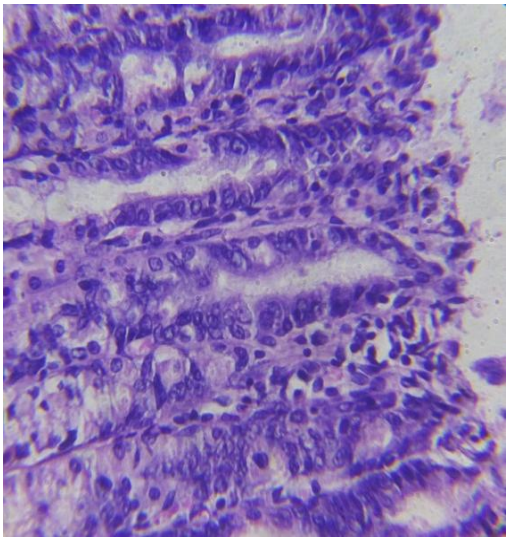




Histopathology of Stomach

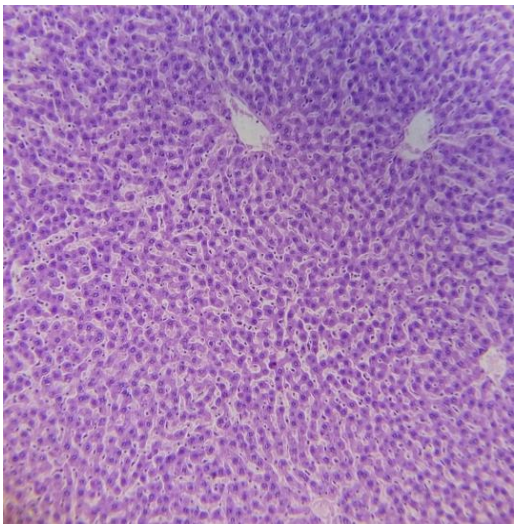
Low Power Magnification 10X **High Power Magnification 40X**

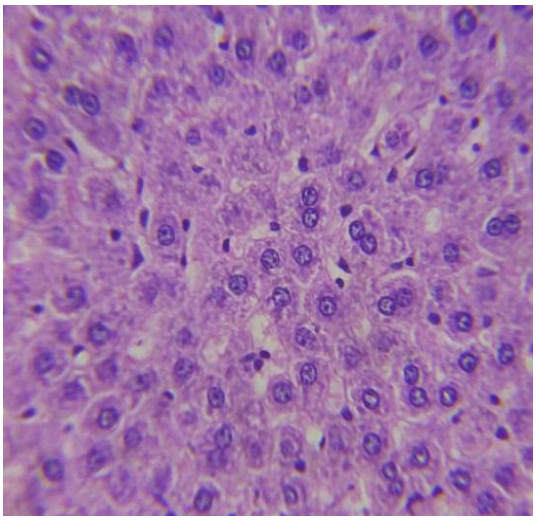




Histopathology of Liver

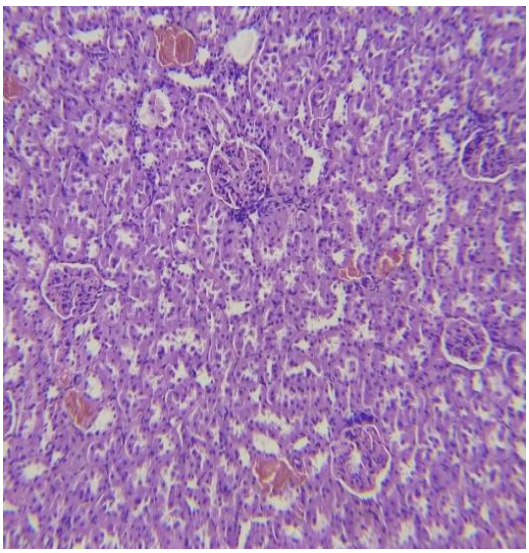
Low Power Magnification 10X **High Power Magnification 40X**



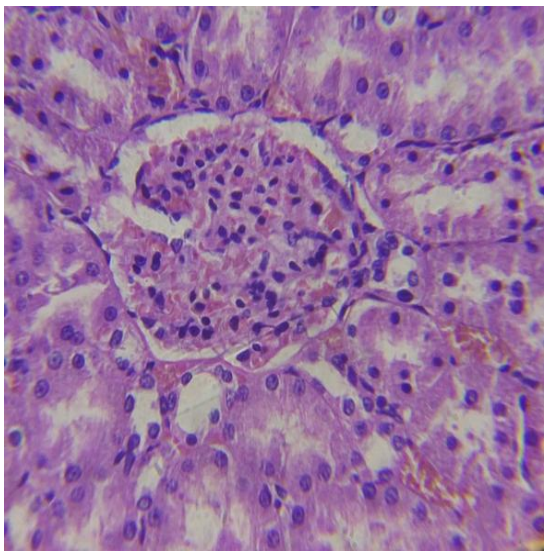


Histopathology of Kidney

Low Power Magnification 10X

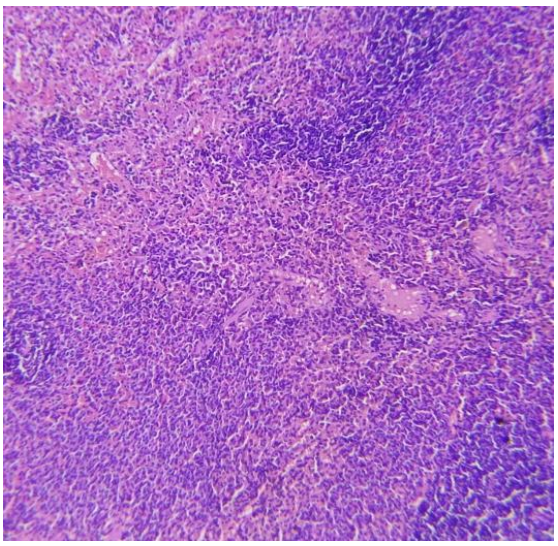


High Power Magnification 40X

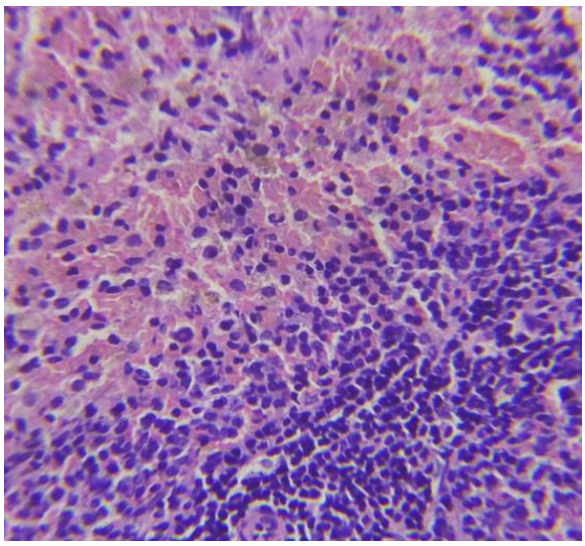


Histopathology of Spleen

Low Power Magnification 10X

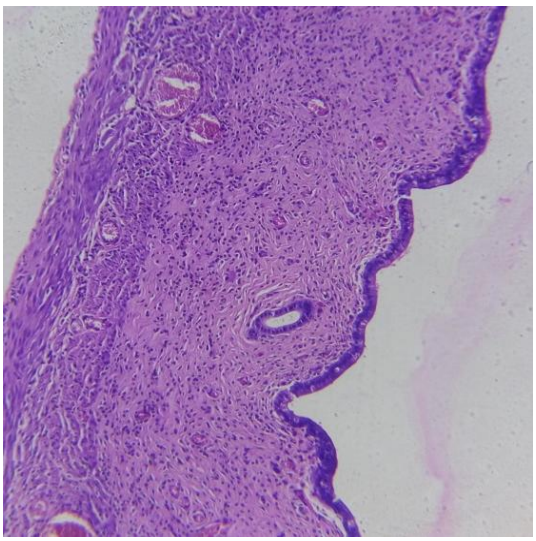


High Power Magnification 40X

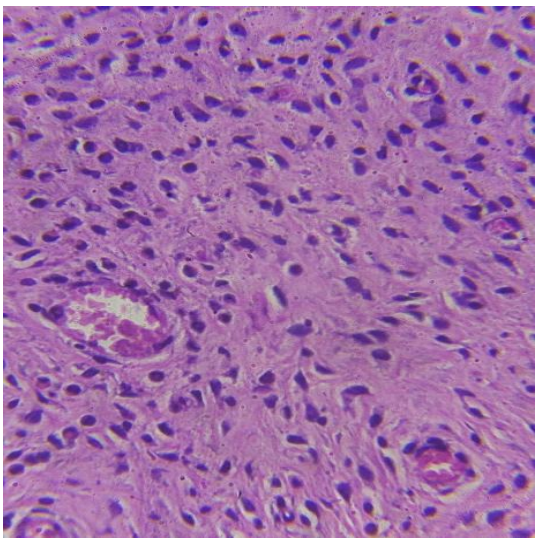


Histopathology of Uterus

Low Power Magnification 10X

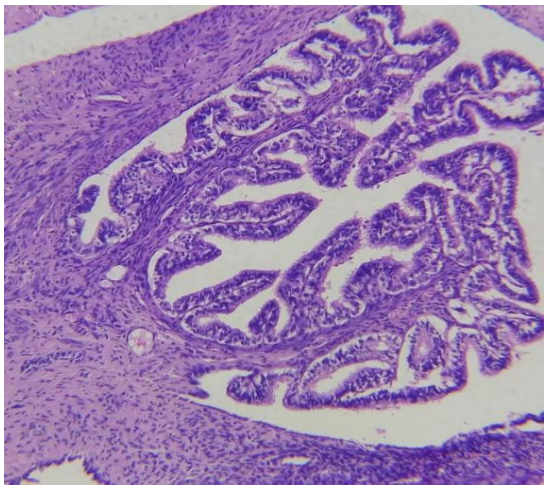


High Power Magnification 40X

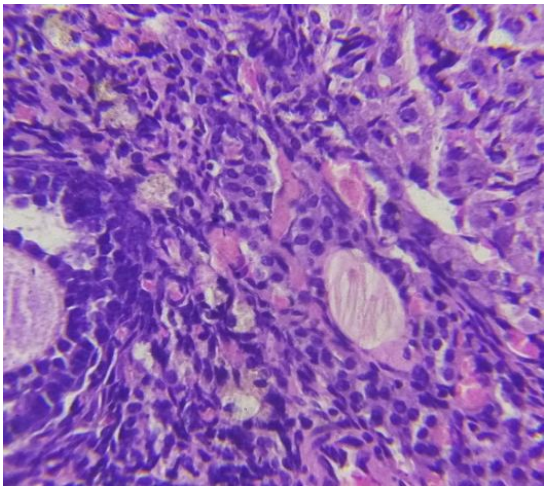


Histopathology of Ovary

Low Power Magnification 10X



High Power Magnification 40X



Results

Heart	Nucleus appears prominent with regular arrangement of fibres. No evidence of pyknotic nucleus
Lung	Inter alveolar septum and alveolar capillary appears normal
Stomach	Mucosal wall appears normal with regular arrangement of connective tissue
Liver	Section of liver showing normal, homogenous, intact hepatic parenchyma; hepatic lobules, with normal central vein.
Kidney	Normal renal structure with rounded renal corpuscles formed of the Glomerulus (G) and the Bowman's capsule (B) surrounded with Proximal Convoluted Tubule (PCT), Distal Convoluted Tubule (DCT) and Collecting Duct (CD).
Spleen	No signs of immunological activities Marginal sinus (MS) of the spleen and its sinus lining cells appears normal
Uterus	Appearance of endometrium, myometrium and uterine glands was normal
Ovary	Follicular cells, cytoplasm and nucleus appears normal

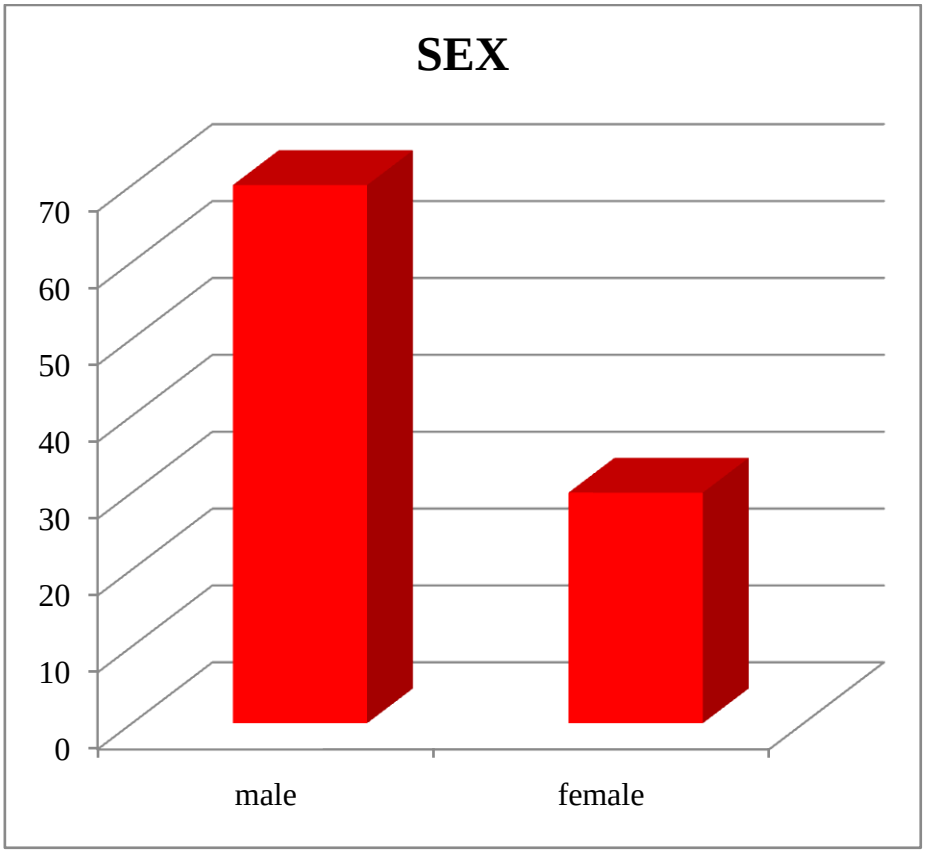
CLINICAL STUDY

The observation and results were studied and tabulated under the following heading.

1. Sex distribution
2. Age distribution
3. Occupational status
4. Diet habits
5. Thinai reference
6. Kaalam distribution
7. Yakkai Ilakkanam (Physical Constitution)
8. Duration of illness
9. Clinical features
10. Distributions of three thodams
11. UdarKattukkal reference
12. En Vagaithervugal
13. Neerkkuri reference
14. Neikkuri reference

SEX DISTRIBUTION

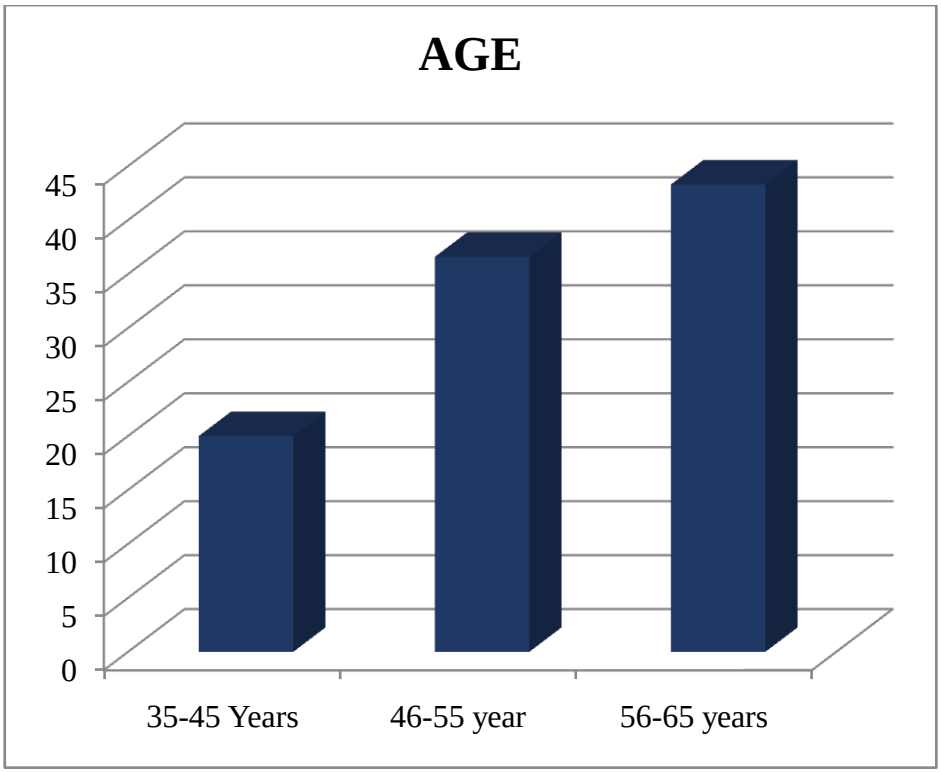
S.NO	SEX DISTRIBUTION	NO OF CASES	PERCENTAGE
1.	Male	21 Male	70%
2.	Female	9 Female	30%



Observation: Among the 30 patients selected for this study, 70% were males and 30% females.

AGE GROUP:

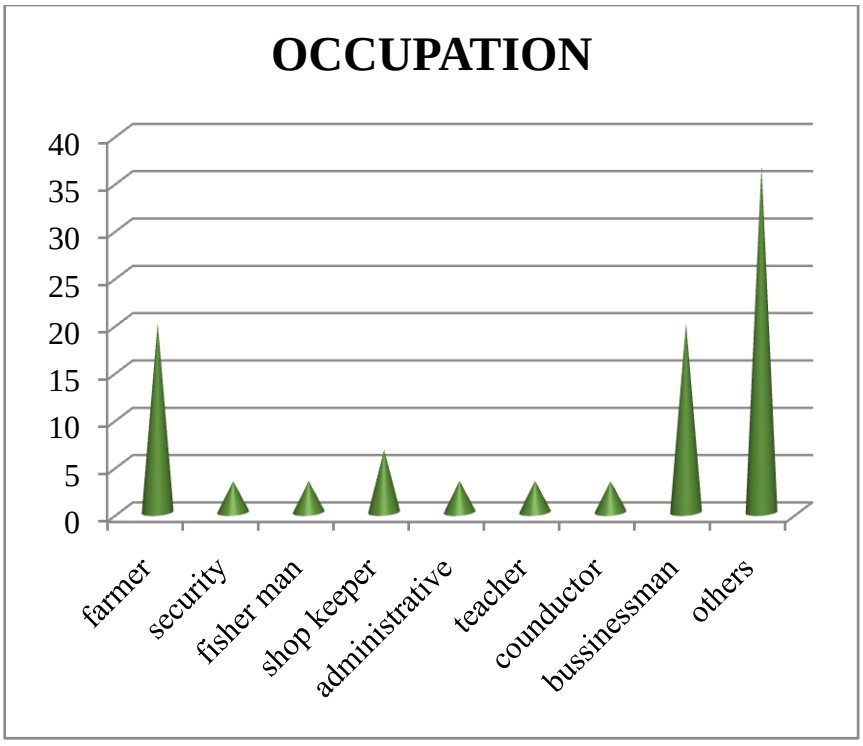
S.NO	AGE	NO OF CASES	RESULTS
1.	35-45 years	6	20.1%
2.	46-55 years	11	36.6%
3.	56-65 years	13	43.3%



Observation: The patients were selected from all age groups as given above and the maximum numbers of patients were in the age between 56 and 65yrs.

OCCUPATIONAL STATUS:

SL. NO	NATURE OF WORK	NO. OF CASES	PERCENTAGE
1.	Farmer	6	20%
2.	Security	1	3.3%
3.	Fisher man	1	3.3%
4.	Shop keeper	2	6.6%
5.	Administration Work	1	3.3%
6.	Teacher	1	3.3%
7.	Conductor	1	3.3%
8.	Businessman	6	20%
9.	Others	11	36.6%

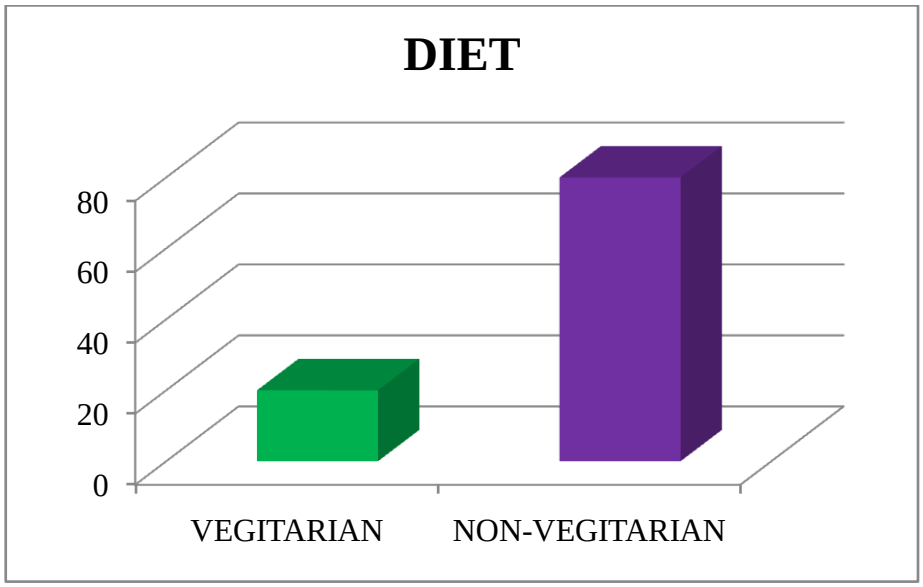


Observation:

Out of 30 patients reported, 20% of patients were work in agriculture, 3.3%of patients were work in security, fishermen, teacher, conductor, administrative work,6.6 % of patients were work in shopkeeper.36.6% of patients were work in other field. The results did not declare DU as an occupational related disease.

DIET HABITS

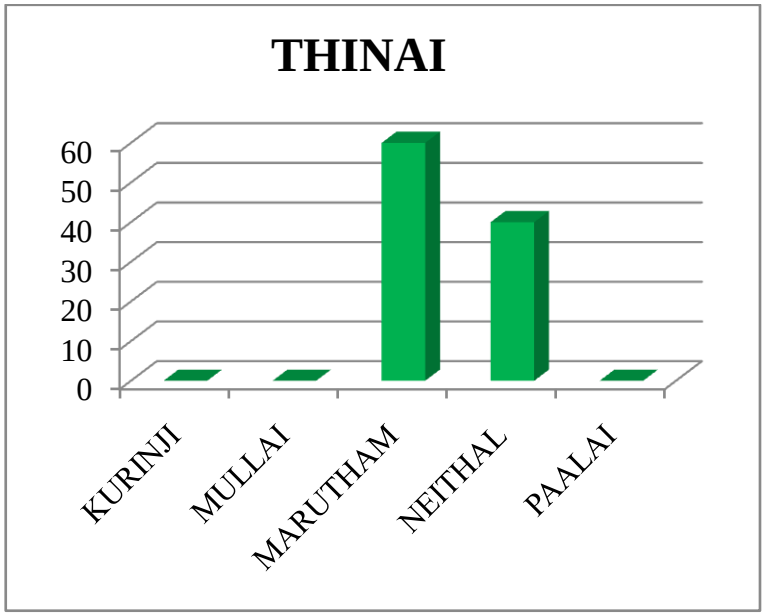
S.NO	DIETRY HABITS	NO OF CASES	RESULTS
1.	Vegetarian	6	20%
2.	Non vegetarian	24	80%



Observation: 80% of the patients were non-vegetarians.

THINAI

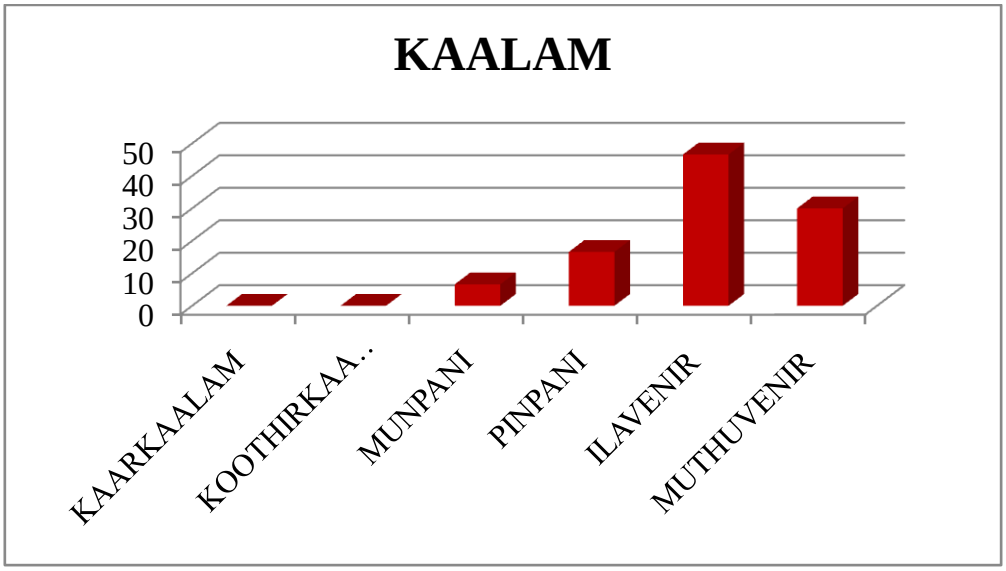
S.NO	THINAI	NO OF CASES	RESULTS
1.	Kurinji	-	-
2.	Mullai	-	-
3.	Marutham	18	60%
4.	Neithal	12	40
5.	Paalai	-	-



Observation: 60% of the patients were from *Neithal* (Coastal Area) and (40%) from *Marutham* (Fertile Land).

KAALAM DISTRIBUTION

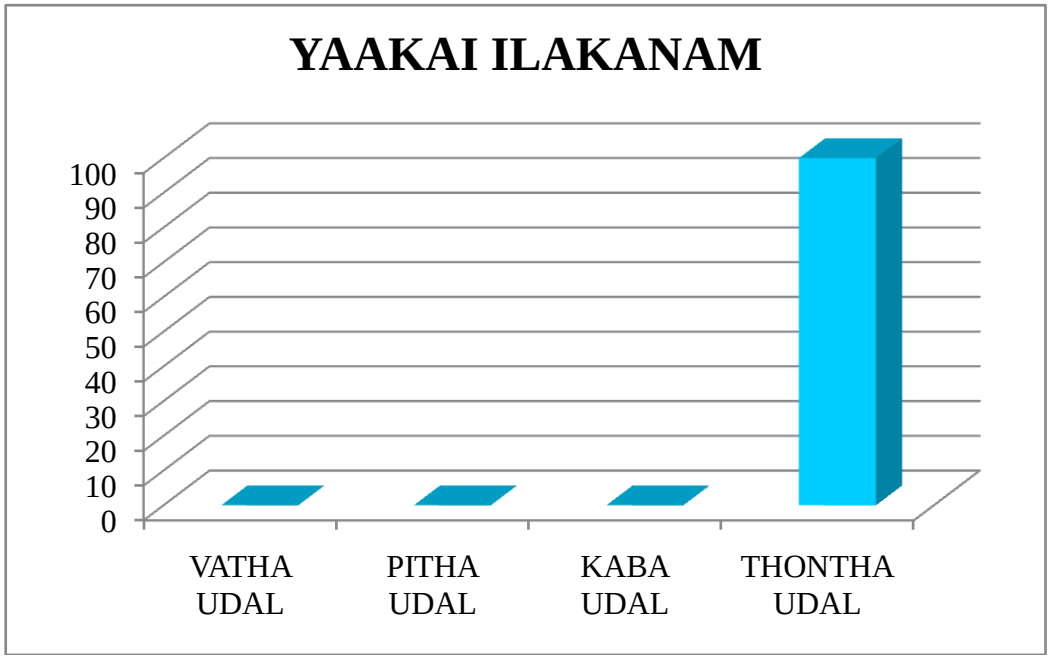
S.NO	KAALAM	NO OF CASES	RESULTS
1.	Kaar kaalam	-	-
2.	Koothir kaalam	-	-
3.	Ilavenir kaalam	14	46.6
4.	Muthuvenir	9	30.2
5.	Mun pani	2	6.6
6.	Pin pani	5	16.6



Observation: 75% of the patients admitted in *Ilavenilkaalam* and the remaining 25% patients were admitted in *Pinpanikaalam*.

YAAKAI ILAKKANAM(PHYSICAL CONSTITUENTS):

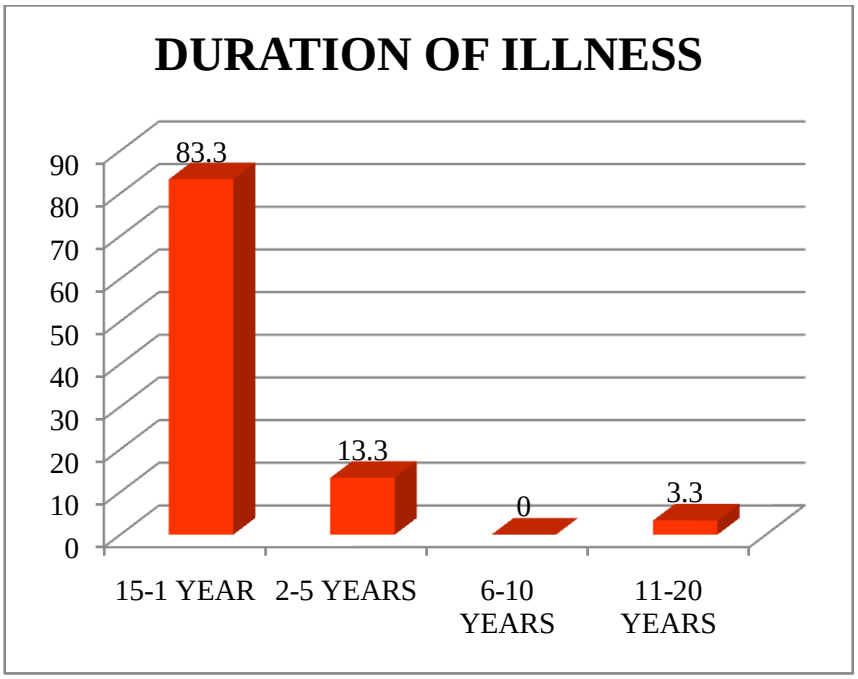
S.NO	YAAKAI ILAKANAM	NO OF CASES	RESULTS
1.	Vatha udal	-	
2.	Pitha udal	-	
3.	Kaba udal	-	
4.	Thontha udal	30	100%



Observation: All the patients (100%) had *Thontha udal*.

DURATION OF ILLNESS:

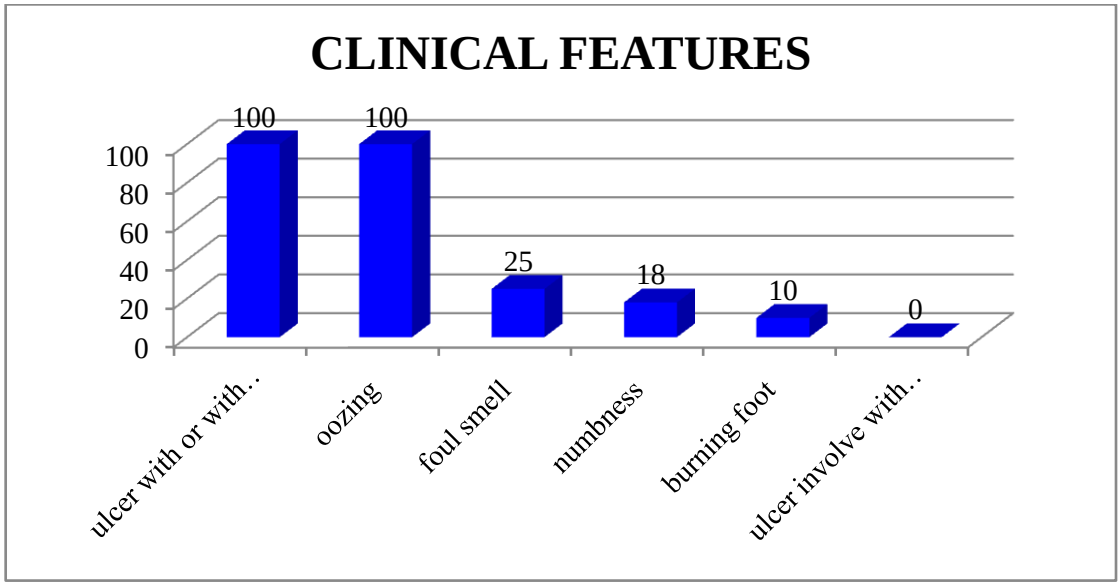
S.NO	DURATION OF ILLNESS	NO OF CASES	RESULTS
1.	15 days – 1 year	25	83.3%
2.	2 – 5 years	4	13.3%
3.	6-10 years	-	-
4.	11-20 years	1	3.3%



Observation: 83.3% of the patients were suffering sudden onset within the years.

CLINICAL FEATURES

S.NO	CLINICAL FEATURES	NO OF CASES	RESULTS
1.	Ulcer with or without pain	30	100%
2.	Oozing	30	100%
3.	Foul smell	25	83.3%
4.	Numbness of foot	18	60%
5.	Burning sensation	10	33.3%
6.	Ulcer involve with muscle,tendon,bone.	-	-
7.	Osteomyelitis	-	-



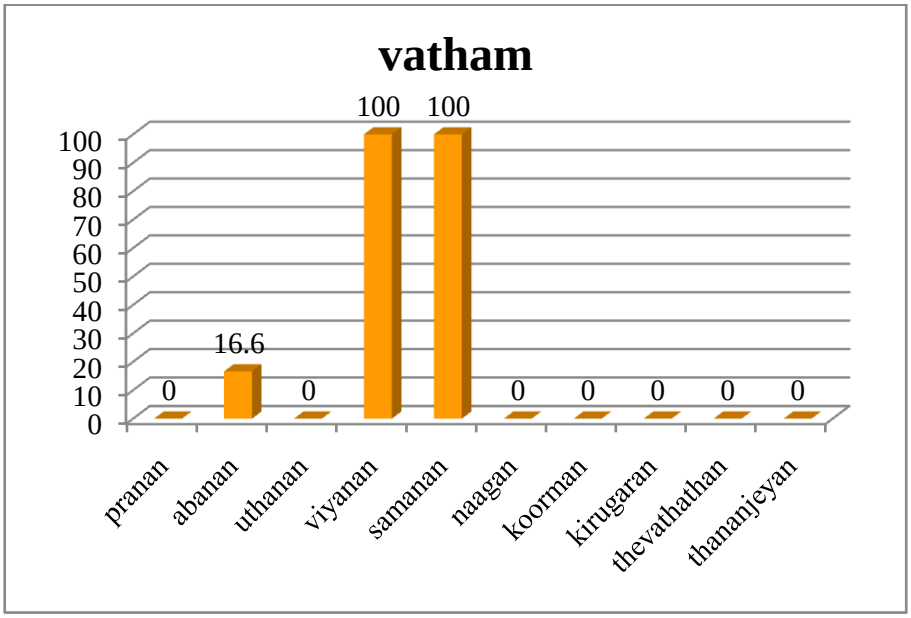
Observation:

Among the 30 patients, 100% of cases with the symptoms of ulcer with or without pain and oozing,83.3% of cases with the symptoms of foul smell,16% of patients were numbness foot,33.3% of patients with the symptoms of burning foot.

DISTRIBUTION OF MUKKUTRAM:

VATHAM:

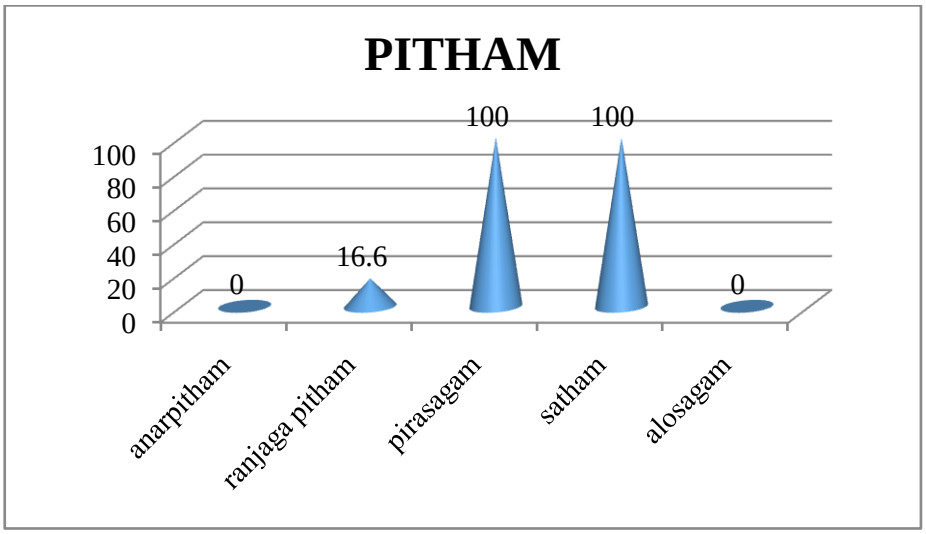
S.NO	VATHAM	NO OF CASES	RESULTS
1.	Pranan	-	-
2.	Abanan	5	16.6%
3.	Uthanan	-	-
4.	Viyanan	30	100%
5.	Samanan	30	100%
6.	Naagan	-	-
7.	Koorman	-	-
8.	Kirugaran	-	-
9.	Thevathathan	-	-
10.	Thananjeyan	-	-



Observation: *Samaanan* and *Viyaanan* were affected in all the 30 patients. *Abanan* were affected in 5 patients respectively.

PITHAM:

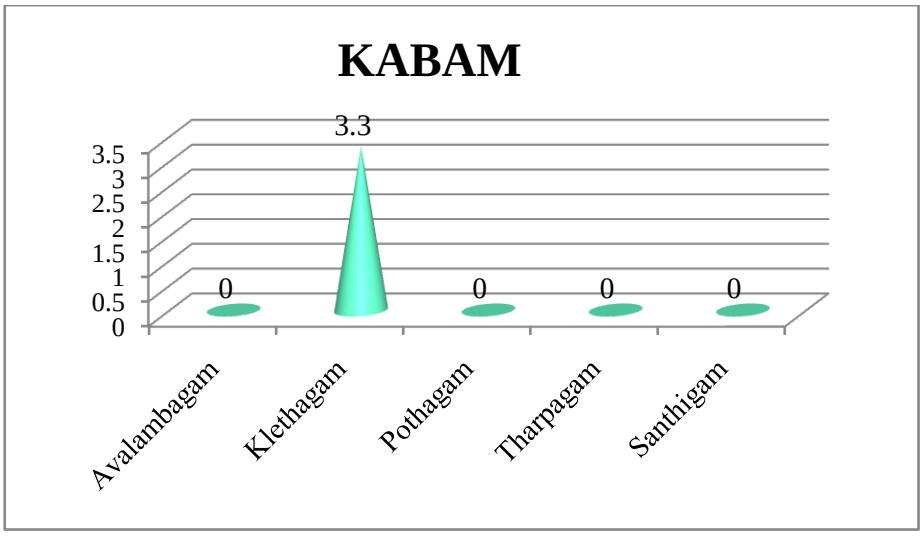
S.No	Pitham	No Of Cases	Results
1.	Anarpitham	-	-
2.	Ranjaga Pitham	5	16.6%
3.	Pirasagam	30	100%
4.	Aalosagam	-	-
5.	Sathagam	30	100%



Observation: *Saathaga pitham* and *Pirasaga pitham* were affected in all the cases.*Ranjaga pitham affected* 5 patients respectively.

KABAM:

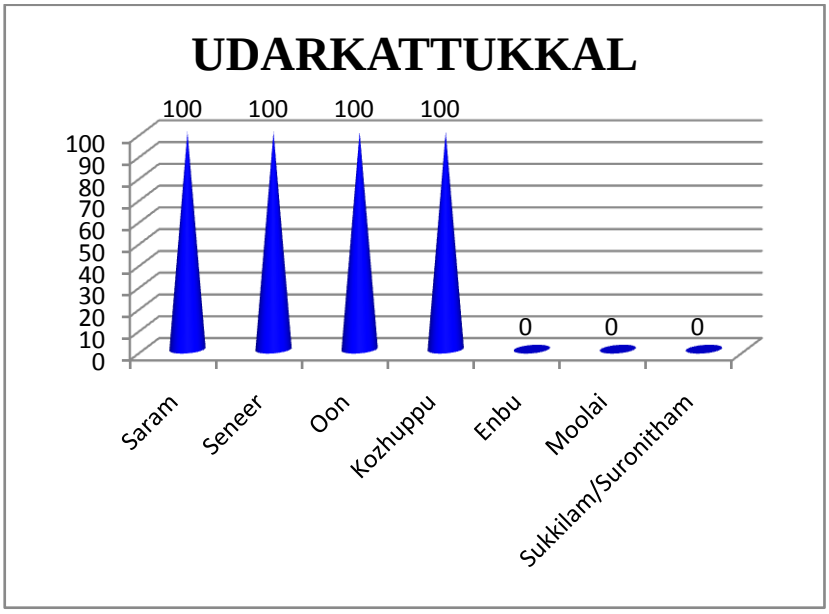
S.NO	KABAM	NO OF CASES	RESULTS
1.	Avalambagam	-	-
2.	Klethagam	1	3.3%
3.	Pothagam	-	-
4.	Tharpagam	-	-
5.	santhigam	-	-



Observation: In *Kabam klethagam* was affected in 1 patient.

UDAR KATTUGAL:

S.NO	UDAR KATTUGAL	NO OF CASES	RESULTS
1.	Saram	30	100%
2.	Seneer	30	100%
3.	Oon	30	100%
4.	Kozhuppu	30	100%
5.	Enbu	-	-
6.	Moolai	-	-
7.	Sukkilam/suronitham	-	-



Observation: Among 30 patients, *Saaram ,Seneer, oon, kozhuppu* were affected in all the cases.

ENVAGAI THERVUGAL:

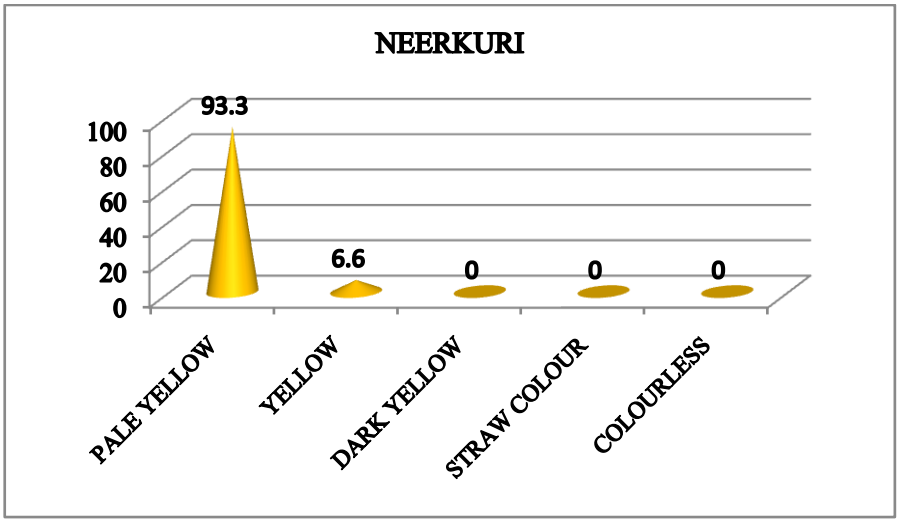
S.NO	ENVAGAI THERVUGAL	NO OF CASES	RESULTS
1.	NAADI NADAI		
	Vathapitham	15	50%
	Pithavatham	10	33.3%
	Kabavatham	5	16.6%
	Kabapitham	-	-
2.	Sparisam	-	-
3.	Naa	-	-
4.	Niram	-	-
5.	Mozhi	-	-
6.	Vizhi	-	-
7.	Malam	5	12.5%
8.	Moothiram	5	12.5%

OBSERVATION:

The *Naadinadai* seen in *Madhumega viranam* patients were *Vathapitham* 50%, *Pithavatham* 33.3 %, *Kabavatham* 16.6%.*Malam and Moothiram* were affected 12.5% of patients.

NEERKURI REFERENCE

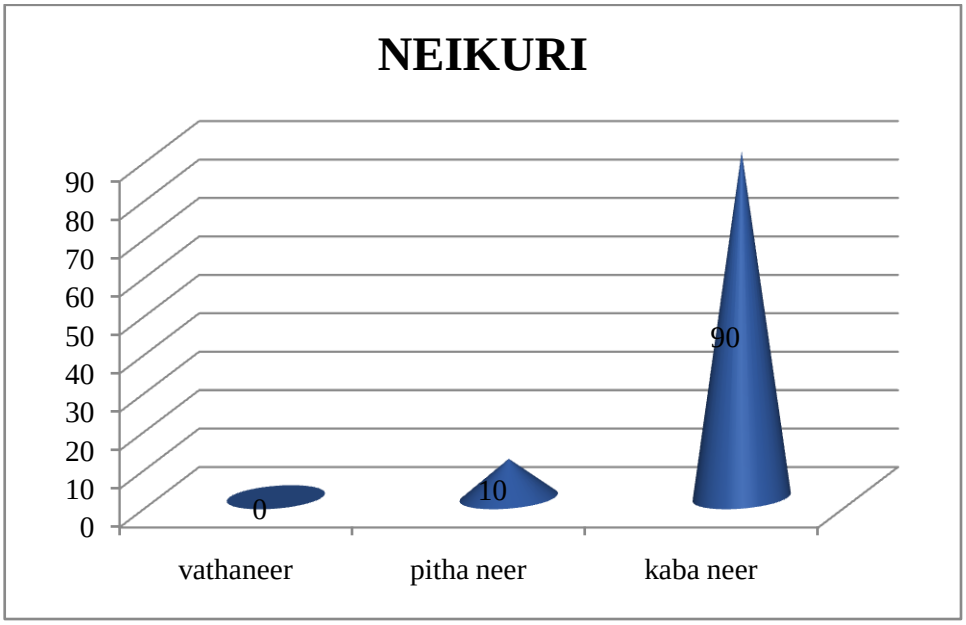
S.NO	NEERKURI	NO OF CASES	RESULTS
1.	Pale yellow	28	93.3%
2.	Yellow	2	6.6%
3.	Straw colour	-	-
4.	Dark yellow	-	-
5.	Colourless	-	-



Observation: In this study 93.3% of the patients had *Neerkkuri* with pale yellow, 6.6% of Patients had yellow in colour.

NEIKURI:

S.NO	NEIKURI	NO OF CASES	RESULTS
1.	Vatham (Aravena neendathu)	0	0
2.	Pitham (Aazhi pol paraviyathu)	3	10%
3.	Kabam (Muthothu nindrathu)	27	90%



Observation: In this study 90% of the patients had *Neikuri* with *kabam (muththothu nindrathu),* 10% patients had pattern of *pitha neer(Aazhipol paraviyathu)*.

OUT COME
BATES GENSEN WOUND ASSESSMENT TOOL

S.NO	OP/IP NO	NAME	AGE/ SEX	WOUND SCALE		RESULTS
				BT	AT	
1.	J74639	V.Devadas	61/M	29	13	GOOD
2.	0069	S.Kumari	59/F	53	13	GOOD
3.	J85814	Murugan	54/M	38	17	MODERATE
4.	J17629	T.Govindhan	56/M	33	13	GOOD
5.	J91684	Palaniappan	54/M	42	16	MODERATE
6.	D94812	A.Venugopalan	65/M	51	25	MODERATE
7.	J96164	G.Rajendran	57/M	31	13	GOOD
8.	K691	R.Kumaraguru	65/M	50	13	GOOD
9.	K00455	M.Ravi	50/M	38	30	POOR
10.	J99448	G.Ravi	45/M	48	13	GOOD
11.	K05003	R.Subramaniyan	63/M	64	25	MODERATE
12.	K05039	A.Santha	56/F	35	13	GOOD
13.	K10900	R.Ramadoss	59/M	30	25	POOR
14.	K09067	V.Radha	63/F	29	13	GOOD
15.	0411	P.Subramani	65/M	39	13	GOOD
16.	J32794	P.Mayanathan	64/M	43	20	MODERATE
17.	J42982	G.Baskaran	48/M	33	13	GOOD
18.	K199215	Egambaram	45/M	43	20	MODERATE
19.	K20157	A.Vasantha	40/F	45	35	POOR

20.	K04483	Kalyani	50/F	40	30	POOR
21.	K19718	Deivanai	53/F	33	13	GOOD
22.	K20390	V.Shanthi	52/F	43	13	GOOD
23.	K23414	V.Ragu	40/M	30	20	POOR
24.	K25805	Parimala	55/F	39	13	GOOD
25.	J22165	Sundaraj	54/M	35	30	POOR
26.	I73587	Dhayalan	54/M	45	35	POOR
27.	K23594	Venkatesh	41/M	38	17	MODERATE
28.	K30093	Philip	58/M	42	13	GOOD
29.	K27535	Chandra	52/F	44	13	GOOD
30.	K14536	Annamalai	43/M	35	20	POOR

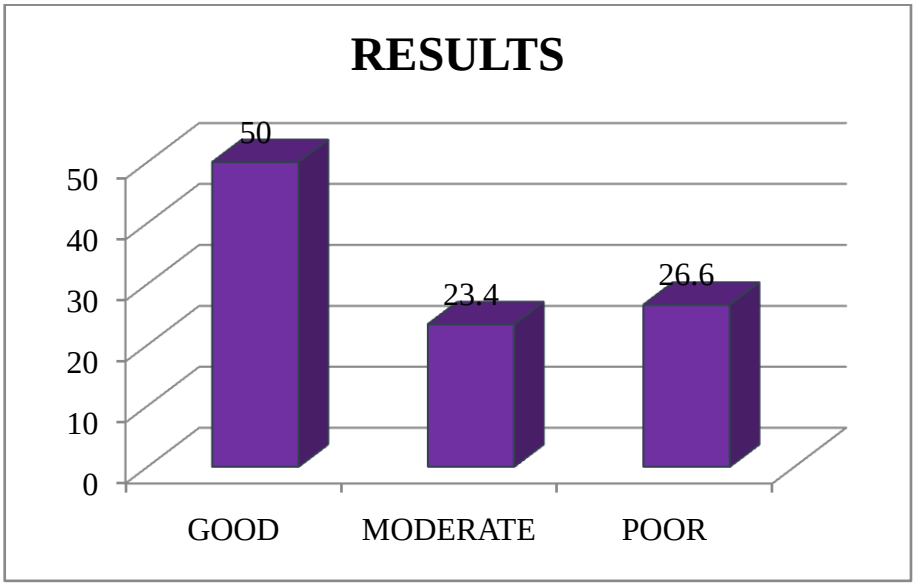
OUTCOME:

BATES GENSEN WOUND ASSESSMENT TOOL

RESULTS:

The trial drug *Gandhi mathirai* (Internal) and *Sagala ranagalukum Kalimbu* (External) were given to 30 patients for 48 days.

S.NO	RESULTS	NO OF CASES	RESULTS
1.	GOOD	15	50%
2.	MODERATE	7	23.4%
3.	POOR	8	26.6%



Observation: The trial drug *Gandhimathirai* (Internal) and *Sagalaranagalukum Kalimbu* (External) were given to 30 patients for 48 days.Good improvement was observed in 15 patients (50%), moderate improvement in 7 patients (23.4%), and mild improvement in 8 (26.6%) cases.

BEFORE TREATMENT **AFTER TREATMENT**

Mr. R.Kumaraguru65/M

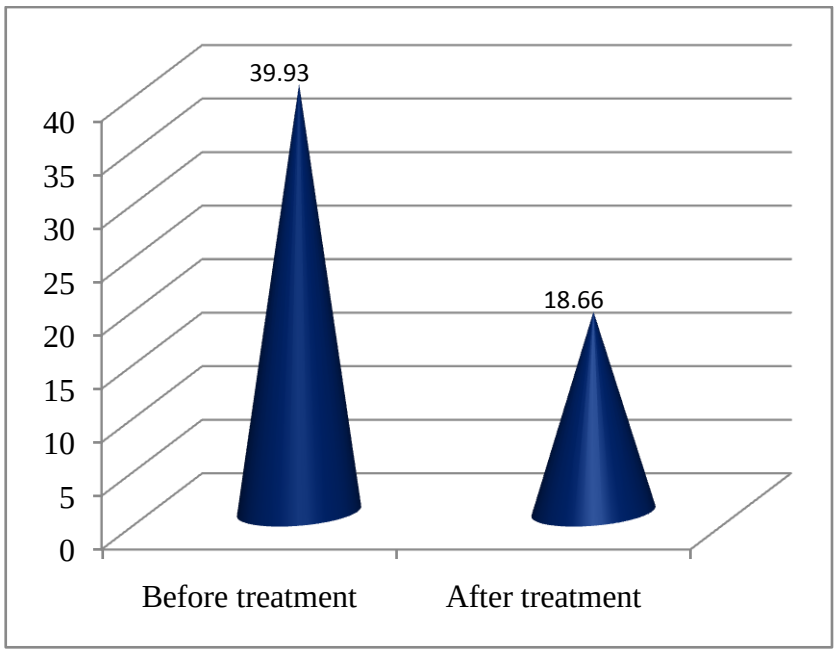
Mrs.S.Kumari 59/F

Mrs. V.Shanthi52/F

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired't' test was performed for determining the significance between before and after treatment.

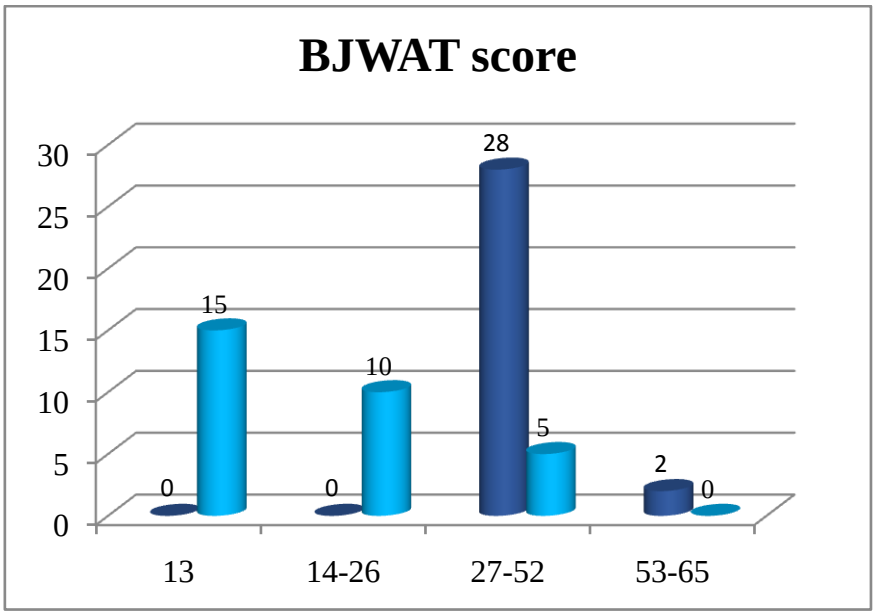
VARIABLE	Obs	MEAN±SD	t value	P value
Before treatment	30	39.93±8.072	t=11.9576	< 0.0001
After treatment	30	18.66±7.288		



The mean± standard deviation of BJWAT score at before and after treatment were 39.93±8.072and 18.66±7.288 respectively which is statistically significant (t=11.9576, p=0.0001).

REDUCTION OF BJWAT SCORE BEFORE AND AFTER TREATMENT

BJWAT SCORE	NO OF CASES	
	BEFORE TREATMENT	AFTER TREATMENT
13	0	15
14-26	0	10
27-52	28	5
53-65	2	0



According to BJWAT scoring, before treatment 28 patients were score between the no on 27-52 and 2 patients were score between 53-65.After treatment 15 patients was score 13,10 patients were scored 14-26,5 patients were scored 27-52.

LABORATORY INVESTIGATION BEFORE AND AFTER TREATMENT

S.NO	OP/IP NO	NAME	AGE/ SEX	HB(gm/dl)		TOTAL RBC COUNT (MILLION/CU.MM)		ESR (MM/HOUR)		TOTAL WBC (CELLS/CU.MM)	
				BT	AT	BT	AT	BT	AT	BT	AT
1	J74639	V.Devadas	61/M	12.9	12.1	4.6	4.8	16/34	2/8	8500	8100
2	0069	S.Kumari	59/F	11.3	11.2	3.9	4.0	60/120	20/40	11900	11000
3	J85814	Murugan	54/M	15.6	15	5.4	5	4/10	2/10	5700	6000
4	J17629	T.Govindhan	56/M	13.2	12.6	4.8	4.6	10/20	10/20	8000	6600
5	J91684	Palaniappan	54/M	11.3	9.9	4.9	4.4	32/66	20/40	8600	10,700
6	D94812	A.Venugopalan	65/M	11.5	12.0	4.2	4.2	20/40	20/40	5400	5600
7	J96164	G.Rajendran	57/M	12.0	12.3	4.4	4.5	40/82	20/40	8100	7500
8	K691	R.Kumaraguru	65/M	12.6	12.8	4.6	4.0	60/122	30/60	9800	8000
9	K00455	M.Ravi	50/M	12.0	12.1	4.0	4.0	10/20	10/20	54000	6700
10	J99448	G.Ravi	45/M	14.2	13.6	5.4	5.2	10/22	20/42	7100	6200
11	K05003	R.Subramaniyam	63/M	10.3	9.8	3.8	3.5	40/84	30/60	7200	7100
12	K05039	A.Santha	56/F	14.5	14.0	5.3	5.1	22/46	10/20	10400	11400
13	K10900	R.Ramadoss	59/M	12.4	13.0	4.7	4.6	6/12	2/4	9100	6800
14	K09067	V.Radha	63/F	11.8	12.3	4.2	4.5	16/34	16/34	11200	11400
15	0411	P.Subramani	65/M	11.8	11.8	4.2	4.2	50/100	20/40	6200	7600

16	J32794	P.Mayanathan	64/M	12.2	13.2	4.2	4.5	40/82	20/40	6000	6100
17	J42982	G.Baskaran	48/M	14.3	15.4	5.0	5.0	4/12	4/12	7900	7700
18	K199215	Egambaram	45/M	12.2	13.0	4.4	4.0	3/6	2/4	8900	8800
19	K20157	A.Vasantha	40/F	11.0	11.5	5.1	5.0	4/10	3/6	8600	8800
20	K04483	Kalyani	50/F	13.1	13.5	4.6	4.6	30/60	10/20	12000	10200
21	K19718	Deivanai	53/F	13.6	12.7	5.1	4.6	2/4	2/4	8000	6600
22	K20390	V.Shanthi	52/F	10.7	11.7	3.7	3.9	10/20	10/20	6500	9100
23	K23414	V.Ragu	40/M	15.1	15.0	4.2	4.3	3/10	2/4	6500	6700
24	K25805	Parimala	55/F	12	11	4.3	4.0	2/10	4/6	8600	9500
25	J22165	Sundaraj	54/M	10.3	11.5	4.3	4.2	6/12	3/6	11200	10200
26	I73587	Dhayalan	54/M	11.0	12.5	4.0	3.8	4/8	2/6	9800	11000
27	K23594	Venkatesh	41/M	13	13.5	4.6	4.6	3/6	2/4	11000	10200
28	K30093	Philip	58/M	13.8	14	5.1	5.0	3/6	2/4	6700	6000
29	K27535	Chandra	52/F	11.3	11.3	4.2	4.1	2/4	2/4	7600	8000
30	K14536	Annamalai	43/M	14.1	14.0	4.8	4.6	4/8	2/4	9700	6900

S.NO	OP/IP NO	NAME	AGE/SEX	SGOT(IU/L)		SGPT(IU/L)		ALKALINE PHOSPHATASE	
				BT	AT	BT	AT	BT	AT
1	J74639	V.Devadas	61/M	12	13	10	12	95	95
2	0069	S.Kumari	59/F	9.4	7.8	21.6	14.5	85	84
3	J85814	Murugan	54/M	15	16	117	14	68	66
4	J17629	T.Govindhan	56/M	12	12	16	15	85	90
5	J91684	Palaniappan	54/M	18	14	29	21	110	90
6	D94812	A.Venugopalan	65/M	10	9	6	5	134	90
7	J96164	G.Rajendran	57/M	16	18	25	12	96	90
8	K691	R.Kumaraguru	65/M	16	13.2	44	15.4	192	163
9	K00455	M.Ravi	50/M	20	18	17	15	60	70
10	J99448	G.Ravi	45/M	12	18	17	15	131	131
11	K05003	R.Subramaniyan	63/M	10	11	10	14	66	61
12	K05039	A.Santha	56/F	23	38.5	24	32	100	127
13	K10900	R.Ramadoss	59/M	10	17	22	20	89	90
14	K09067	V.Radha	63/F	19	11	23	10	68	67
15	0411	P.Subramani	65/M	16	13.5	19	9.9	86	92

16	J32794	P.Mayanathan	64/M	15	16	9	12	80	78
17	J42982	G.Baskaran	48/M	14	18	17	19	100	41
18	K19921	Egambaram	45/M	18	15	20	22	85	80
19	K20157	A.Vasantha	40/F	20	17	14	20	60	65
20	K04483	Kalyani	50/F	13	14	20	19	90	87
21	K19718	Deivanai	53/F	10	10	11	13	100	112
22	K20390	V.Shanthi	52/F	32	17	30	16	48	41
23	K23414	V.Ragu	40/M	10	12	20	16	89	80
24	K25805	Parimala	55/F	30	25	21	17	182	156
25	J22165	Sundaraj	54/M	7.1	10	17	12	94	85
26	I73587	Dhayalan	54/M	17	34	20	32	85	80
27	K23594	Venkatesh	41/M	11	10	15	15	64	60
28	K27535	Chandra	52/F	35	22	29	22	108	79
29	K30093	Philip	58/M	10	10	8	8	103	85
30	K14536	Annamalai	43/M	13	13	15	16	68	70

S.NO	OP/IP NO	NAME	AGE/SEX	TOTAL BILIRUBIN		DIRECT BILIRUBIN		INDIRECT BILIRUBIN	
				BT	AT	BT	AT	BT	AT
1.	J74639	V.Devadas	61/M	1.1	1.1	0.4	0.4	0.7	0.7
2.	0069	S.Kumari	59/F	0.23	0.36	0.12	0.14	0.1	0.2
3.	J85814	Murugan	54/M	0.5	0.2	0.2	0.3	0.3	0.1
4.	J17629	T.Govindhan	56/M	0.4	0.5	0.2	0.2	0.3	0.3
5.	J91684	Palaniappan	54/M	0.4	0.4	0.2	0.2	0.2	0.2
6.	D94812	A.Venugopalan	65/M	0.5	0.2	0.2	0.3	0.3	0.6
7.	J96164	G.Rajendran	57/M	0.3	0.55	0.1	0.06	0.2	0.49
8.	K691	R.Kumaraguru	65/M	0.4	0.31	0.1	0.14	0.3	0.17
9.	K00455	M.Ravi	50/M	0.6	0.3	0.2	0.1	0.4	0.1
10.	J99448	G.Ravi	45/M	0.6	0.6	0.3	0.1	0.3	0.3
11.	K05003	R.Subramaniyan	63/M	0.4	0.3	0.2	0.2	0.2	0.1
12.	K05039	A.Santha	56/F	0.6	0.7	0.2	0.1	0.4	0.6
13.	K10900	R.Ramadoss	59/M	0.3	0.13	0.2	0.1	0.4	0.3
14.	K09067	V.Radha	63/F	0.4	0.3	0.2	0.1	0.2	0.2
15.	0411	P.Subramani	65/M	0.2	0.70	0.4	0.27	0.3	0.4

16.	J32794	P.Mayanathan	64/M	0.5	0.7	0.2	0.3	0.3	0.4
17.	J42982	G.Baskaran	48/M	0.8	0.6	0.3	0.2	0.5	0.4
18.	K199215	Egambaram	45/M	0.8	0.5	0.2	0.1	0.3	0.2
19.	K20157	A.Vasantha	40/F	0.5	0.2	0.1	0.3	0.3	0.1
20.	K04483	Kalyani	50/F	0.2	0.1	0.3	0.2	0.6	0.4
21.	K19718	Deivanai	53/F	0.8	0.8	0.2	0.3	0.6	0.5
22.	K20390	V.Shanthi	52/F	0.4	0.7	0.20	0.3	0.2	0.4
23	K23414	V.Ragu	40/M	0.2	0.2	0.3	0.1	0.4	0.2
24.	K25805	Parimala	55/F	0.32	0.4	0.15	0.2	0.17	0.2
25.	J22165	Sundaraj	54/M	0.2	0.2	0.1	0.2	0.1	0.1
26.	I73587	Dhayalan	54/M	0.4	0.3	0.1	0.1	0.3	0.2
27.	K23594	Venkatesh	41/M	0.9	0.8	0.3	0.1	0.6	0.2
28.	K30093	Philip	58/M	0.8	0.3	0.2	0.1	0.6	0.2
29.	K27535	Chandra	52/F	0.7	0.9	0.4	0.3	0.3	0.6
30.	K14536	Annamalai	43/M	0.5	0.6	0.2	0.2	0.3	0.1

S.NO	OP/IP NO	NAME	AGE/SEX	BLOOD SUGAR				UREA		CREATININE (mg/dl)	
				FASTING(mg/dl)		POSTPRANDIAL(mg/dl)					
				BT	AT	BT	AT	BT	AT	BT	AT
1.	J74639	V.Devadas	61/M	129	126	237	235	33	30	1.0	1.0
2.	0069	S.Kumari	59/F	347	224.4	417	380	35.1	27.5	1.12	1.24
3.	J85814	Murugan	54/M	81	100	251	233	13	13	1.0	0.8
4.	J17629	T.Govindhan	56/M	78	109	148	138	20	21	0.8	0.6
5.	J91684	Palaniappan	54/M	307	150	411	280	23	17	1.1	1.2
6.	D94812	A.Venugopalan	65/M	295	160	427	280	29	30	0.8	1.0
7.	J96164	G.Rajendran	57/M	170	142	341	378	21	28	1.0	1.0
8.	K691	R.Kumaraguru	65/M	173	208	357	312	13.0	18.7	1.0	0.89
9.	K00455	M.Ravi	50/M	118	110	327	288	17	17	0.9	0.5
10.	J99448	G.Ravi	45/M	225	132	348	298	16	18	0.9	0.5
11.	K05003	R.Subramaniyan	63/M	197	170	331	309	21	17	1.0	1.2
12.	K05039	A.Santha	56/F	181	233	233	303	25	21	1.0	0.8
13.	K10900	R.Ramadoss	59/M	200	120	343	280	25	27	1.0	1.0
14.	K09067	V.Radha	63/F	188	177	205	282	41	40	1.0	1.0
15.	0411	P.Subramani	65/M	214	59.4	350	187	17.8	22.1	1.15	1.06

16.	J32794	P.Mayanathan	64/M	97	107	114	122	22	35	1.2	1.2
17.	J42982	G.Baskaran	48/M	226	194	418	320	19	23	1.0	0.9
18.	K19921	Egambaram	45/M	156	129	280	230	16	18	0.6	0.8
19.	K20157	A.Vasantha	40/F	110	120	160	180	33	30	0.7	0.8
20.	K04483	Kalyani	50/F	150	120	321	280	32	30	1.0	0.8
21.	K19718	Deivanai	53/F	289	263	407	425	17	21	0.8	0.9
22.	K20390	V.Shanthi	52/F	124	108	186	189	17	21	0.5	0.8
23.	K23414	V.Ragu	40/M	120	95	280	233	16	18	1.0	1.0
24.	K25805	Parimala	55/F	159	150	312	300	22	18	0.8	0.8
25.	J22165	Sundaraj	54/M	110	100	197	200	33	30	1.2	1.0
26.	I73587	Dhayalan	54/M	120	98	181	140	17	15	1.1	1.1
27.	K23594	Venkatesh	41/M	217	180	320	250	19	18	1.2	1.0
28.	K27535	Chandra	52/F	161	118	205	199	29	17	0.9	0.9
29.	K30093	Philip	58/M	266	180	456	250	40	40	1.0	1.0
30.	K14536	Annamalai	43/M	125	351	160	239	30	30	1.3	1.0

S.NO	OP/IP NO	NAME	AGE/ SEX	URINE (F)		URINE (PP)		ALBUMIN		DEPOSITS			
										EPITHELIAL CELLS		PUS CELLS	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	J74639	V.Devadas	61/M	Nil	Nil	+	+	Nil	Nil	1-2	1-2	1-2	1-2
2	0069	S.Kumari	59/F	++	+	++	+	Nil	Nil	3-5	2-3	3-5	1-2
3	J85814	Murugan	54/M	Nil	Nil	++	++	Nil	Nil	1-2	1-2	1-2	1-2
4	J17629	T.Govindhan	56/M	Nil	Nil	Nil	+	Nil	Nil	2-4	1-2	1-2	1-2
5	J91684	Palaniappan	54/M	++	Trace	+++	++	Nil	Nil	2-4	1-2	4-6	3-5
6	D94812	A.Venugopalan	65/M	++	++	+++	+++	Nil	Nil	3-5	1-2	3-5	3-4
7	J96164	G.Rajendran	57/M	+	+	++	++	Nil	Nil	2-3	1-2	2-3	2-6
8	K691	R.Kumaraguru	65/M	+	+	++	++	Nil	Nil	4-6	2-4	10-12	4-5
9	K00455	M.Ravi	50/M	+	+	++	++	Nil	Nil	1-2	1-2	1-2	1-2
10	J99448	G.Ravi	45/M	+	+	++	+	Nil	Nil	1-2	1-2	2-3	2-4
11	K05003	R.Subramaniyan	63/M	Nil	Nil	++	++	Nil	Nil	1-2	1-2	1-2	4-5
12	K05039	A.Santha	56/F	+	+	-	++	Nil	Nil	2-3	2-3	2-4	2-4
13	K10900	R.Ramadoss	59/M	+	Nil	++	++	Nil	Nil	2-3	3-6	1-2	1-2
14	K09067	V.Radha	63/F	+	+	++	++	Nil	Nil	1-2	2-4	1-2	2-4
15	0411	P.Subramani	65/M	Nil	Nil	Trace	+	Nil	Nil	2-4	2-3	4-6	1-2

16	J32794	P.Mayanathan	64/M	Nil	Nil	Nil	Nil	Nil	Nil	2-4	2-4	1-2	1-2
17	J42982	G.Baskaran	48/M	++	++	+++	+++	Nil	Nil	1-2	1-2	1-2	1-2
18	K19921	Egambaram	45/M	Nil	Nil	+	+	Nil	Nil	2-3	1-2	1-2	1-2
19	K20157	A.Vasantha	40/F	Nil	Nil	+	+	Nil	Nil	2-3	2-4	1-2	1-2
20	K04483	Kalyani	50/F	+	+	++	++	Nil	Nil	2-6	2-3	1-2	1-2
21	K19718	Deivanai	53/F	++	Nil	+++	++	Nil	Nil	Nil	Nil	2-3	1-2
22	K20390	V.Shanthi	52/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4	4-5	1-2	8-10
23	K23414	V.Ragu	40/M	Nil	Nil	+	+	Nil	Nil	2-4	2-3	1-2	1-2
24	K25805	Parimala	55/F	+	Trace	++	+++	Nil	Nil	2-6	3-5	3-5	3-5
25	J22165	Sundaraj	55/F	Nil	Nil	Nil	+	Nil	Nil	1-2	2-3	2-4	1-2
26	I73587	Dhayalan	54/M	Nil	Nil	+	+	Nil	Nil	1-2	2-3	1-2	4-5
27	K23594	Venkatesh	54/M	Nil	Nil	++	++	Nil	Nil	1-2	2-3	2-3	1-2
28	K27535	Chandra	41/M	+	Nil	++	Nil	Nil	Nil	2-3	1-2	1-2	2-3
29	K30093	Philip	52/F	+	Nil	++	++	Nil	Nil	10-15	2-3	3-5	1-2
30	K14536	Annamalai	58/M	+	Nil	+++	++	Nil	Nil	1-2	2-3	2-3	1-2

DISCUSSION

Diabetic ulcer is one of the most severe manifestations of diabetes. A disease of great importance to public health due to its high incidence and prevalence and because of the high socioeconomic impact that it brings, since it is difficult to treat and requires prolonged work absenteeism.

The raw drugs of *Gandhi mathirai* were identified and authentication certificate was obtained. Then the raw drugs were purified and GM was prepared as per the text Agasthiya vaithiya sinthamani. Phytosterols, Flavonoids, Amino acids, glycosides, Phenolic Compounds and Tannins, Saponins, Carbohydrates were present in this drug.

The drug is free of microbial contamination, aflatoxins and pesticide residues. The heavy metals were not detected (arsenic, mercury, cadmium, lead). HPTLC finger printing analysis of the sample GM reveals the presence of three prominent peaks corresponds to presence of six versatile phyto components present with in it. Rf value of the peaks ranges from 0.06 to 0.93. Further the peak 2 occupies the major percentage of area of 56.11 % which denotes the abundant existence of such compound. Followed by this peak 1 and 2 occupies the percentage area of 16.15 and 13.36%. The Acute and 90 days repeated oral toxicity studies did not show any toxic effects in the animals.

Clinical study:

For this study, 30 patients were selected and patients were treated in the OPD/IPD department of Sirappu Maruthuvam, in Ayothidoss Pandithar Hospital of National Institute of Siddha, Tambaram Sanatorium, Chennai – 600 047.

The trial drug “GM” was given for 48 days. OPD patients were requested to visit the hospital once in 7 days. In each and every visit clinical assessment and prognosis were recorded. Laboratory investigations were done for all the cases before and after treatment. There were no variations in hepatic, renal and other parameters.

Based on various criteria, the data were collected and tabulated. The criteria were sex predominance, age distribution, occupation, dietary habits and incidence of the disease with reference to thinai, seasonal variation,clinical manifestations and Envagai thervu, Neerkuri and Neikuri.

30 patients of both genders were recruited for this study. Among the 30 cases, 21(70%) were males and 9 (30%) were females. Generally Diabetic ulcer occurs in both sexes, but a higher prevalence was noticed in males. In this study, more number of male cases was reported.

Out of 30 cases, 20.1% patients were between 35 to 45 years, 36.6% patients between 46 to 55 years, 43.3% patients between 56 and 65 years. There were no differences in age in the onset of psoriasis between men and women with DU.

Out of 30 patients reported, 20% of patients were work in agriculture, 3.3%of patients were work in security, fishermen, teacher, conductor, administrative work,6.6 % of patients were work in shopkeeper.36.6% of patients were work in other field. The results did not declare DU as an occupational related disease.

In this present study, 60% of the patients were from Marutham (fertile Land) and the remaining (40%) from Neithal (Coastal) area. Considerable numbers of patients were reported from Marutham. In this present study, 46.6% patients were affected in Muthuvenil kaalam.

Among the 30 patients selected for this study, 80% were non-vegetarian.20% patients were vegetarian. In this present study reveals DU occurs due to improper diet control and physical activity.

Among the 30 patients selected for this study, 83.3% of patients were affect the duration between 15 days – 1 year, 13.3 % of cases were 2-5 years,3.3% of cases were long duration of symptoms. This study revels DU can occurs sudden onset and also prolong duration.

Among the 30 patients, 100% of cases with the symptoms of ulcer with or without pain and oozing,83.3% of cases with the symptoms of foul smell,16% of patients were numbness foot,33.3% of patients with the symptoms of burning foot.

In Vaatham, Samanan and Viyanan were found to be affected in all the 30 patients. Abananwas found to be affected in 16.6% of patients. Among 30 patients, Saaram and Seneer, Oon were affected in all the cases.

In Envagaithervugal, Malam was found affected in 5 cases. The Naadinadai seen in DU patients were Vaathapitham 50%, Pithavaatham 33.3 %, Kabavatham 16.6%.

The haematological and biochemical parameters were tested for the patients treated with GM and it was found that there was no difference before and after treatment. This vouches for the safety of the trial drug administered as the values were well within the normal limits.

The quantity variables were expressed as Mean ± Standard Error of Mean and qualitative data as percentage. A probability value of <0.05 was considered to be statistically significant.

According to BJWAT scoring, before treatment 28 patients were score between the no on 27-52 and 2 patients were score between 53-65.After treatment 15 patients was score 13,10 patients were scored 14-26,5 patients were scored 27-52.

The mean± standard error of mean of BATES JENSAN WOUND ASSESSMENT TOOL score before and after treatment were 39.93 ± 8.072 and 18.66±7.288 respectively which is statistically significant (t= 11.9576, p <0.0001).

The outcome of this study was clinically observed by BATES JENSAN WOUND ASSESSMENT TOOL Score, which showed encouraging results of good improvement in 15 patients (50%), moderate improvement in 7 patients (23.4%), and poor improvement in 8 (26.6%) cases.

In this study, no adverse events were observed during the course of the treatment. At the end of the study, all the patients were advised to attend out-patient department of Sirappu Maruthuvam of NIS for further follow-up.

SUMMARY

The raw drugs of GM were identified and authentication certificate was obtained.

The physicochemical analysis of the prepared drug revealed that it was in the standard quality.

HPTLC were done to identify phyto- chemicals and their Rf values were calculated.

The toxic elements like Mercury, Arsenic and Cadmium are not detected. The Lead present in GM is within the WHO permissible limit.

The study shows that GM did not produce any toxic effect in repeated oral toxicity study for 90 days.

This study has been approved by NIS/IEC/2016/11-15/14.10.2016

The disease diabetic ulcer was taken for the clinical study with *Gandhi mathirai* and*Sagala ranagalukum kalimbu* 30 cases were selected based on the approved protocol.

Animal studies were done after obtaining approval from the Animal Ethical Committee (IAEC). Hence the study was safely executed on patients and there was no adverse drug reactions noted during the study period.

The detailed study on diabetic ulcer with reference to its aetiology, pathogenesis, investigations, clinical features, diagnosis and treatment with trial drug was done.

According to BJWAT scoring, before treatment 28 patients were score between the no on 27-52 and 2 patients were score between 53-65.After treatment 15 patients was score 13,10 patients were scored 14-26,5 patients were scored 27-52.

The results were observed by BJWAT score. Among the 30 cases treated, 15(50%) cases showed Good improvement, 7(23.4%) cases showed Moderate improvement and 8(26.6%) cases showed Poor improvement.

The mean± standard error of mean of BJWAT score at before and after treatment were 39.93 ± 8.072 and 18.66±7.288 respectively which is statistically significant (t= 11.9576, p <0.0001).

CONCLUSION

The herbo-mineral formulation Gandhi mathirai (GM) exhibited no toxicity on Repeated 90 days toxicity study.

The present clinical study confirms the efficacy and safety of the trial drug “Gandhi mathirai” which is Siddha herbo-mineralformulation. It was found to be good resulting on *Madhumega viranam* patients in reducing clinical signs and symptoms like ulcer with and without pain, oozing present, foul smell, numbness foot, burning sensation.

The quantitative outcome of BATES JENSAN WOUND ASSESSMENT score shows there is significant reduction between at the start and end of treatment i.e from 39.93 ± 8.072 and 18.66±7.288.The qualitative outcome shows there is 50% of cases had shown good improvement, 23.4% of cases had shown moderate improvement and remaining 26.6% of cases had shown poor improvement.

According to BJWAT scoring, before treatment 28 patients were score between the no on 27-52 and 2 patients were score between 53-65.After treatment 15 patients was score 13,10 patients were scored 14-26,5 patients were scored 27-52.

From the above results, the trail drug “Gandhi mathirai” was responded well in the treatment of *Madhumega viranam*.

As a conclusion it can be stated that the Siddha herbo-mineral formulation GM can be used as a safe and efficacious drug towards the management of *Madhumega viranam*.

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69, Anna Salai, Guindy, Chennai - 600 032.

*This Certificate is awarded to Dr/Mr/Mrs.....*VIDHYA.R.....

For participating as ~~Resource Person~~ / Delegate in the Twenty First Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 25th to 29th April 2016.

Dr.N.KABILAN, MD(S),
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संसथान
Ministry of AYUSH- आयुष मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियमचेन्नई -600 047
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ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 14.10.2016

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. R.Vidhya – I year, Dept.of Sirappu Maruthuvam	
Protocol Title:- Preclinical and open Clinical trial of Gandhi Mathirai (Internal Medicine) and Sagala Ranangalukum Kalimbu (External Medicine) in the treatment of Madhumega Viranam (Diabetic Ulcer).	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-15/ 14.10.2016**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

(Dr.V.Subramanian)
Chairman

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA ★ CHENNAI 600 047

CERTIFICATE

This is certify that the project title Preclinical and Open clinical trial of *Gandhi Mathirai* (Internal) Sagala Ranangalukum Kalimbu (External) In the Treatment of *Madhumega Viranam* (Diabetic Ulcer) **has been approved by the IAEC.** Approval No: NIS/IAEC-III/40/29092016
Total No of animals: Rats 89 (40M+49F)

Prof.Dr.V.Banumathi
Name of Chairman/Member Secretary IAEC:

Prof.Dr.K. Nachimuthu
Name of CPCSEA nominee:

Signature with date
V. Banumathi 29/9/16
Chairman/Member Secretary of IAEC:

29/9/2016
CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

Name of the PI: Dr.R.Vidhya

Name of the Department: Sirappu Maruthuvam

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Gandhi mathirai"** (Internal) and **Sagala Ranangalukum kalimbu** (External) taken up for Post Graduation Dissertation studies by **Dr.R.Vidhya** M.D.(S), II year, Department of Sirappu Maruthuvam, 2017, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Momordica dioica Roxb. ex Willd. (Cucurbitaceae), Fruit

Typhonium trilobatum (L.) Schott. (Araceae), Tuber

Terminalia chebula Retz. (Combretaceae), Fruit

Sesbania sesban (L.) Merr. (Fabaceae), Leaves

Vateria indica Linn. (Dipterocarpaceae), Oleoresin

Quercus infectoria Oliv. (Fagaceae), Gall

Terminalia belerica Roxb. (Combretaceae), Fruit

Acacia catechu Wild. (Mimosaceae), Wood extract

MEDICINAL BOTANY ★ CHENNAI 600 047 ★ National Institute of Siddha

Certificate No: NISMB2892017

Date: 22-3-17

Authorized Signatory

Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
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F.No:NIS/Gunapadam/Au/2017/4 27.03.17

AUTHENTIFICATION CERTIFICATE

Certified that the samples submitted for identification by **Dr. R. Vidhya**, II year PG scholar, Dept. of Sirappu Maruthuvam, National Institute of Siddha, Chennai - 47, are identified as **Gandhagam(Sulphur), Lingam(Cinnabar), Rasakarpooram(Merucury subchloride), Miruthdar singi(Galena sulphie of Lead)** on the basis of macroscopic character.

This certificate is issued for the purpose of preparing her dissertation medicine in Gunapadam laboratory, NIS.

Dr. S. Visweswaran, M.D (s)
Head of Department
Department of Gunapadam
National Institute of Siddh
Tambaram Sanatorium, Chenn

NATIONAL INSTITUTE OF SIDDHA

(An Autonomous body under Ministry of AYUSH, Govt. of India)
Tambaram Sanatorium, Chennai- 600 047

Workshop on

"BASIC RESEARCH TECHNIQUES AND PRACTICES INVOLVED IN LABORATORY ANIMAL CARE"

06 -10 February 2017

CERTIFICATE

This is to certify that Dr. R. Vidhya has participated as Delegate/~~Resource~~ Person in the workshop on "Basic Research Techniques and Practices involved in Laboratory Animal Care" held on 06-10 February, 2017 at National Institute of Siddha, Chennai-47, Tamilnadu.

Dr. V. Suba
Organizing Secretary

Dr. P. Muthusamy
Veterinary Consultant

Prof. Dr. V. Banumathi
Director / Chairperson

தேசிய கருத்தரங்கம்

சித்த மருத்துவத்தில் புற மருத்துவ முறைகள்

SIDDHA REGIONAL RESEARCH INSTITUTE

(Under Central Council for Research in Siddha, Chennai.
Ministry of Ayush, Government of India)
Kuyavarpalayam, Puducherry - 605 013.

Certificate No : SRRI/NCPM/2017/409

Certificate

This is to certify that Dr./~~Sh.~~/~~Km.~~/~~Smt.~~ **Vidhya. R**

has Presented a Paper/~~Poster~~ entitled

Evaluation of Karanool therapy application in Pilonidal sinus (Purai Pun) - A case study

in the National Conference on Pura Maruthuvam - External Therapies in Siddha System of Medicine organized by Siddha Regional Research Institute, Puducherry held on 9th & 10th December, 2017 at Dr. APJ Abdul kalam JIPMER Auditorium, Puducherry.

Organising Secretary **Convenor** **Chairman**

Clinical Trial Details (PDF Generation Date :- Mon, 09 Jul 2018 06:07:05 GMT)

CTRI Number	CTRI/2018/04/013023 [Registered on: 04/04/2018] - **Trial Registered Retrospectively**
Last Modified On	23/03/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	gandhi mathirai internal sagalaranangalukum kalimbu external in the management of madhumegaviranam
Scientific Title of Study	preclinical and open clinical trial of gandhi mathirai and sagala Ranangalukum kalimbu in the treatment of madhumega viranam

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	R Vidhya
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai. Ayothidass pandithar hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai. Kancheepuram TAMIL NADU 600047 India
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Email	rvmahalakshmi85@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> self

Primary Sponsor

Primary Sponsor Details	
Name	R vidhya
Address	ayothidass pandithar hospital, bNational Institute of Siddha,tambaram sanatorium,chennai
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
r vidhya	National Institute Of Siddha	ayothidass pandithar hospital,national institute of siddha,tambaram sanatorium, chennai DEPARTMENT OF SIRAPPU M MARUTHUVAM,opd 3 Kancheepuram TAMIL NADU	7708858617 dr.vidhyarajendran@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	14/10/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	patient with diabetic ulcer with or without pain

Intervention / Comparator Agent

Type	Name	Details
Intervention	gandhi mathirai (internal) sagala ranangalukum kalimbu (external)	gandhi mathirai is a herbo mineral preparation with dosage of 65mg(bid) with thirikadugu chooranam for 48 days sagala ranagalukum kalimbu is a herbo mineral preparation applied externally twice a day for 48days
Comparator Agent	not applicable	not applicable

Inclusion Criteria

Inclusion Criteria	
Age From	35.00 Year(s)
Age To	65.00 Year(s)
Gender	Both

	Details	patient include with diabetic ulcer ulcer with or without pain fibrogenous exudates edema inflammation and induration willing to give specimen of blood for investigation permit to take photograph

Exclusion Criteria

Exclusion Criteria	
Details	extensive and localised gangrene require amputation osteomyelitis deep ulceration with bone and joint involvement varicose ulcer tuberculuos ulcer any other systemic illness

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
bates- jensen wound assessment tool	1- 48 days

Secondary Outcome

Outcome	Timepoints
To assess the safety of trial drug	1-48 days

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30
Phase of Trial	Phase 2
Date of First Enrollment (India)	11/01/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	not yet published
Brief Summary	**gandhi mathirai and sagala Ranangalukum kalimbu in the treatment of madhumega viranam**

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
CHENNAI – 600 047.

"PRE CLINICAL AND OPEN CLINICAL TRIAL OF *GANDHI MATHIRAI* (INTERNAL MEDICINE) AND *SAGALA RANANGALUKUMKALIMBU* (EXTERNAL MEDICINE) IN THE TREATMENT *OF MADHUMEGA VIRANAM* (DIABETIC ULCER)".

FORM l - SCREENING & SELECTION PROFORMA

SL.NO: **OP/IP NO:**

NAME: **AGE/GENDER:** **CONTACT NO:**

INCLUSION CRITERIA:

Age: 30-65 years	Yes/No
Patient includes diabetic ulcer	Yes/No
Ulcer with or without Pain	Yes/No
Itching	Yes/No
Edema	Yes/No
Fibrinous exudates in the lesions	Yes/No
Hyper pigmentation	Yes/No
Inflammation & Induration	Yes/No
Willing to give specimen of blood for the investigation	Yes/No
Permit to take photograph.	Yes/No

EXCLUSION CRITERIA:

Extensive and localized Gangrene require amputation	Yes/No
Osteo Myelitis	Yes/No
Deep ulceration with bone, joint involvement	Yes/No
Varicose ulcer	Yes/No
Hansen's disease	Yes/No
Tuberculous ulcer	Yes/No
Any other systemic illness	Yes/No

ADMITED TO TRIAL: YES /NO OPD ☐ IPD ☐ If yes, serial No: ☐☐

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

"PRE CLINICAL AND OPEN CLINICAL TRIAL OF *GANDHI MATHIRAI* (INTERNAL MEDICINE) AND *SAGALA RANANGALUKUMKALIMBU* (EXTERNAL MEDICINE) IN THE TREATMENT *OF MADHUMEGA VIRANAM* (DIABETIC ULCER)".

PRINCIPAL INVESTIGATOR: Dr. R.Vidhya

FORM II – CLINICAL RESEARCH FORM

STUDY NO: **OP/ IP NO:**

NAME: **AGE/GENDER:**

ADDRESS: **CONTACT NO:**

RELIGION: H / M / C / O

OCCUPATION: **INCOME:**

MARRITAL STATUS: MARRIED ☐ **UNMARRIED** ☐

DATE OF INITIAL ASSESSMENT:

COMPLAINTS & DURATION:

PERSONAL HISTORY:

PERSONAL HABITS	**YES**	**NO**	**IF YES SPECIFY DURATION**	**AMOUNT/Qty**
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:

FAMILY HISTORY:

Whether this problem runs in family? 1. Yes ☐ 2. No ☐

If yes, mention the relationship of affected person(s)

1._____ 2._____

DIETARY HABIT: 1.Vegetarian ☐ 2.Non-vegetarian ☐

MENSTURAL HISTORY AND OBSTETRIC HISTORY:

FORM II a

GENERAL EXAMINATION

		BEFORE	**AFTER**
1. Body weight [Kg]	:		
2. Height [cms]	:		
3. Body Temperature [^{0}F]	:		
4. Blood Pressure (mm/Hg)	:		
5. Pulse Rate /min	:		
6. Heart Rate / min	:		
7. Respiratory Rate /min	:		

		Yes	**No**	**Yes**	**No**
8. Pallor	:	☐	☐	☐	☐
9. Jaundice	:	☐	☐	☐	☐
10. Clubbing	:	☐	☐	☐	☐
11. Cyanosis	:	☐	☐	☐	☐
12. Pedal Edema	:	☐	☐	☐	☐
13. Lymphadenopathy	:	☐	☐	☐	☐
14. Jugular venous pulsation		☐	☐	☐	☐

VITAL ORGANS EXAMINATION:	**Normal**	**Abnormal**	**Normal**	**Abnormal**
1. Heart	☐	☐	☐	☐
2. Lungs	☐	☐	☐	☐
3. Brain	☐	☐	☐	☐
4. Liver	☐	☐	☐	☐
5. Kidney	☐	☐	☐	☐

6. Spleen ☐ ☐ ☐ ☐
7. Stomach ☐ ☐ ☐ ☐

SYSTEMIC EXAMINATION:Normal Abnormal Normal Abnormal

1. Cardio-vascular system ☐ ☐ ☐ ☐
2. Respiratory system ☐ ☐ ☐ ☐
3. Gastro intestinal system ☐ ☐ ☐ ☐
4. Central nervous system ☐ ☐ ☐ ☐
5. Uro-genital system ☐ ☐ ☐ ☐
6. Endocrine system ☐ ☐ ☐ ☐

SIDDHA SYSTEM OF EXAMINATION

1. THEGI (TYPE OF BODY CONSTITUTION):

1. Vaatha udal ☐ 3. Kaba udal ☐
2. Pitha udal ☐ 4.Thontha udal ☐

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji ☐ 3. Paalai ☐
2. Mullai ☐ 4. Neithal ☐
5. Marutham ☐

3. KAALAM:

1. Kaar kaalam ☐ 4. Pinpani kaalam ☐
2. Koothir kaalam ☐ 5. Ilavenil kaalam ☐
3. Munpani kaalam ☐ 6. Muthuvenil kaalam ☐

4. GUNAM:

1. Sathuvam ☐ 2. Rasogunam ☐
3. Thamogunam ☐

5. PORIPULANGAL (SENSORY ORGANS):

	1st day	8th day	15th day	22nd day	29th day	36th day	43r day	49th day
Mei (skin)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Vaai (tongue)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kan (eye)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Mooku (nose)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Sevi (ear)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

6. KANMENDRIYAM (MOTOR ORGANS):

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Kai (upper limb)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kaal (lower limb)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Vaai (speech)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Eruvai (excretory organ)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Karuvai (reproductive organs)	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

7. KOSANGAL (SHEATH):

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Annamayakosam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Pranamayakosam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Manomaya kosam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Vignanamaya kosam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Aananthamayakosam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

8. UYIR THATHUKKAL (THREE HUMOURS):

A. VALI

	1st Day	8th Day	15th day	22nd day	29th day	36th day	43rd day	49th day
Praanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Abaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Viyaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Udhaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Samaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Naagan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Koorman	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kirukaran	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Devathathan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Dhananjeyan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

B) AZHAL

	1st day	8th Day	15th day	22nd day	29th day	36th day	43rd day	49th day
Anarpitham	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Prasakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Ranjagapitham	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Aalosakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Saathakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

C. IYAM:

	1stday	8th day	15th day	22nd day	29thday	36thday	43rd day	49th day
Avalambagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kilethagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Pothagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Tharpagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Santhigam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

9.SEVEN UDAL DHATHUS: (7 SOMATIC COMPONENTS)

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Saaram	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Moolai	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

II. SPARISAM:

1st day	8th Day	15th Day	22nd day	29th day	36th day	43rd day	49th day

III. NAA:[TONGUE]

1st day	8th Day	15th Day	22nd Day	29th Day	36th Day	43rd Day	49th Day

VI.NIRAM: [COMPLEXION]

1. Vaatham ☐ 2. Pitham ☐ 3.Kabam ☐

V.MOZHI: [VOICE]

1. High Pitched ☐ 2. Low Pitched ☐ 3. Medium Pitched ☐

VI.VIZHI: [EYES]

1st Day	8th Day	15th Day	22th Day	29th Day	36th Day	43rd Day	49th Day

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	After treatment
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKURI	Before treatment	After treatment
Aravu (Serpentine fashion)		
Aazhi (Annular/Ringed fashion)		
Muthu (Pearl beaded fashion)		
Kalappu (Mixed fashion)		
Other fashion		

CLINICAL EXAMINATION OF ULCER

INSPECTION:

1. Location:----------
   ----
2. Size :
3. Colour :Normal ☐ Reddish ☐ Black ☐ ☐ Greyish
4. Shape :Regular ☐ Irregular ☐
5. Fibrinous exudate :No ☐ Mild ☐ Moderate ☐ Severe ☐
6. Erythema :Present ☐ Absent ☐
7. Bleeding :Present ☐ Absent ☐
8. Crusting :Present ☐ Absent ☐
9. Inflammation :Present ☐ Absent ☐

10. Induration :Present ☐ Absent ☐

11. Edges :

12. Margin :

		YES	NO
13. Ulcération	:	☐	☐
14. Macule	:	☐	☐
15. Papule	:	☐	☐
16. Pustule	:	☐	☐
17. Blister	:	☐	☐
18. Vesicle	:	☐	☐

19. Pigmentation : Normal ☐ Hypo ☐ Hyper ☐

FORM II B-CLINICAL ASSESSMENT DURING AND AFTER TRIAL

OP/ IP NO: STUDY NO: NAME:

	1st day	**8th Day**	**15th Day**	**22nd Day**	**29th Day**	**36th Day**	**43rd Day**	**49th Day**
Size								
Shape								
Depth								
Inflammation								
Induration								
Surrounding Skin color								
Exudate type								

Exudate amount								
Peripheral oedema								

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSSPANDITHARHOSPITAL

CHENNAI – 600 047.

"PRE CLINICAL AND OPEN CLINICAL TRIAL OF *GANDHI MATHIRAI* (INTERNAL MEDICINE) AND *SAGALA RANANGALUKUMKALIMBU* (EXTERNAL MEDICINE) IN THE TREATMENT *OF MADHUMEGA VIRANAM* (DIABETIC ULCER)".

PRINCIPAL INVESTIGATOR: Dr. R.Vidhya

FORM-III – LABORATORY INVESTIGATIONS PROFORMA

STUDY NO: NAME: OP/IPNO:AGE/GENDER:

BLOOD INVESTIGATIONS		**NORMAL VALUES**	**BEFORE TMT (DATE)**	**AFTER TMT (DATE)**
Hb(gm/dl)		**M:12-15 F:11.5-14**		
T.WBC (cells/cu.mm)		**4000-11000**		
DIFFERENTIAL COUNT (%)	**Polymorphs**	**40-75**		
	Lymphocytes	**20-40**		
	Monocytes	**2-10**		
	Eosinophils	**1-6**		
	Basophils	**0-1**		
T.RBC(million cells/cu.mm)		**M:4.0-5.5 F:3.5-4.5**		
ESR(mm/hour)	**½ hr**	**M:1-13 F:1-20**		
	1 hr			
Blood Investigations		**Normal Values**	**Before TMT (DATE)**	**After TMT (DATE)**
Blood glucose (mg/dl)	**Fasting**	**70-110**		
	PP	**80-140**		
	Random	**80-120**		
RFT (mg/dl)	**Blood urea**	**16-50**		

	Serum creatinine	**0.6-1.2**		
	Serum uric acid	**M:3-9** **F:2.5-7.5**		
LFT (mg/dl)	**Total bilirubin**	**0.2-1.2**		
	Direct bilirubin	**0.1-1.2**		
	Indirect bilirubin	**0.2-0.7**		
	SGOT (IU/L)	**0-40**		
	SGPT (IU/L)	**0-35**		
	Alkaline phosphatase(IU/L)	**80-290**		

Urine investigations	**Before TMT(Date)**	**After TMT (Date)**
Albumin		
Fasting sugar		
PP sugar		
Deposits		
Neerkuri		
Neikuri		

OTHER TEST

HBsAG

VDRL

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL,

CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

"PRE CLINICAL AND OPEN CLINICAL TRIAL OF *GANDHI MATHIRAI* (INTERNAL MEDICINE) AND *SAGALA RANANGALUKUMKALIMBU* (EXTERNAL MEDICINE) IN THE TREATMENT *OF MADHUMEGA VIRANAM* (DIABETIC ULCER)".

FORM V– PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.R.Vidhya

Name of the institute: National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATIONS SHEET FOR PATIENT PARTICIPATED IN THE OPEN CLINICAL TRIAL.

I, Dr.R.Vidhya,studying M.D (Siddha) at National Institute of Siddha, Tambaram Sanatorium is going to do a trial on "*Madhumega viranam*" (Diabetic ulcer).Diabetic ulcer commonly seen in diabetic individual, it is commonly occur in toes, feet particularly in sole, Leg is also affected, In this regard; I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine

"***GANDHI MATHIRAI*****"** (Internal medicine) 1 (b.i.d) and '***SAGALA RANANGALUKUM KALIMBU***" (External medicine) for 48days.

The information I am collecting in this study will remain between you and the principal investigator (I). I will ask you few questions through a questionnaire. I will not write your name on this form. Your name won't be mentioned in the lab investigation form instead a code will be used.The questionnaire will take approximately 20 minutes of your time.

If you want to know more about this study before taking part, you can contact Dr.R.Vidhya, PG Scholar, principal investigator of this study,National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel.No: 91-44-22380789, for rights and participation in the study.

தகவல் படிவம்
தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாஸ் பண்டிதர் மருத்துவமனை–சென்னை–47

மதுமேக விரணம் என்னும் நோய்க்கான கெந்தி மாத்திரை (உள் மருந்து) மற்றும் சகலரணகளுக்கும் களிம்பு(வெளி மருந்து) சித்த மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆய்வாளர் பெயர் : மருத்துவர். இரா.வித்யா,

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்,
தாம்பரம், சானட்டோரியம்,
சென்னை - 47.

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்-இரா.வித்யா),மதுமேக விரணம் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.மதுமேக விரணம் என்னும் நோயானது நோயாளி நீண்ட காலமாக இந்நோயினால் பாதிக்கப்பட்டு அதன் காரணமாக விரணம் உண்டாகி அதில் வலி அல்லது வலி இல்லாமல், குருதி,சிழ்,விக்கம்,தோலின் நிறம் மாறல்,அரிப்பு ஆகிய குறிகுணம் உண்டாக்கும் நோயாகும்.
இந்த ஆராய்ச்சி சம்மந்தமாக சில கேள்விகளை கேட்கவும், தேவையான ஆய்வகபரிசோதனைக்கு தங்களை பரிசோதனைக்கு உட்படுத்தவும் உள்ளேன், அது சம்மந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாய் வைக்கப்படும் என உறுதி அளிக்கிறேன்.இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்படமாட்டாது.இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு எற்படும் பட்சத்தில் தேசிய சித்த மருத்துவ நிறுவனத்தில் தக்க சிகிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சிக்கு தங்களின் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக கெந்தி மாத்திரை 1 இருவேளை (காலை, மாலை) உணவுக்கு பின் 48 நாட்கள் உட்கொள்ள வேண்டும்,வெளிமருந்தாக சகலரணகளுக்கும் களிம்பு.இந்த ஆராய்ச்சியில் நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் விலகி கொள்ளலாம்.இந்த ஆராய்ச்சி சம்மந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் முதன்மை ஆய்வாளரான மருத்துவர் இரா.வித்யா (பட்ட மேற்படிப்பாளார் சிறப்பு மருத்துவ துறை) அணுகவும்.கைபேசி எண்:

மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறபட்டுள்ளது.மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தப்படுகிறது.

NATIONAL INSTITUTE OF SIDDHA

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Principal Investigator: Dr. R.Vidhya

FORM-V – CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely."

Date:

Signature of a witness

(Selected by the participant bearing no connection with the survey team)

Left thumb Impression of the Participant

ஒப்புதல் படிவம்

ஆய்வாளரால்-சான்றளிக்கப்பட்டது

தேசிய சித்த மருத்துவ நிறுவனம்,

அயோத்திதாஸ் பண்டிதர் மருத்துவமனை,சென்னை-47.

மதுமேக விரணம் நோய்க்கான கெந்தி மாத்திரை(உள் மருத்து) மற்றும் சகலரணங்களுக்கும் களிம்பு (வெளிமருந்து) சித்த மருந்துகளின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்-ஆய்வாளரால் சான்றளிக்கப்பட்டுள்ளது

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : **கையொப்பம்:**

இடம் : **பெயர்:**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும்,தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமைத் தெரிந்திருக்கிறேன். நான் என்னுடைய சுகந்திரமாக தேர்வு செய்யும் உரிமைக் கொண்டு மதுமேக விரணம் என்னும் நோய்க்கான **கெந்தி மாத்திரை**(உள் மருந்து) மற்றும் **சகலரணகளுக்கும் களிம்பு**(வெளிமருந்து) சித்த மருந்துகளின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி : **கையொப்பம் :**

இடம் : **பெயர் :**

சாட்சிகாரர் கையொப்பம்:

உறவுமுறை:

விரிவுரையாளர் கையொப்பம்: **துறைத்தலைவர் கையொப்பம்:**

NATIONAL INSTITUTE OF SIDDHA

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CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

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Principal Investigator:Dr.R.Vidhya

FORM VII -A- WITHDRAWAL FORM

1. SERIAL NO OF THE CASE: ……

2. OP / IP NO: .....

3. NAME: ……

4.AGE: ……

5.GENDER:.....

6. DATE OF TRIAL COMMENCEMENT: ……...

7. DATE OF WITHDRAWAL FROM TRIAL: ……..

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes / No
Irregular treatment:	Yes / No
Shift of locality:	Yes / No
Increase in severity of symptoms:	Yes / No
Development of severe adverse drug reactions:	Yes / No
Development of adverse event:	Yes / No

(If YES, give the details of adverse reaction in Form VII -B – Adverse Reaction Form / Pharmaco Vigilance Form)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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Principal Investigator: Dr. R. Vidhya

FORM VII -B – ADVERSE REACTION FORM / PHARMACO VIGILANCE FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF THE ADVERSE REACTION OCCURS:

DESCRIPTION OF ADVERSE REACTION:

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாசர் பண்டிதர் மருத்துவமனை
சென்னை-47

மதுமேக விரணம் நோய்க்கான கெந்தி மாத்திரை(உள் மருத்து) மற்றும் சகலரணங்களுக்கும் களிம்பு (வெளிமருந்து) சித்த மருந்துகளின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆய்வாளர் பெயர் : மருத்துவர். இரா.வித்யா.

படிவம் VIIIஉணவு பரிந்துரை படிவம்

காய்கறிகள்:

சாப்பிடக் கூடியவை	**சாப்பிடக் கூடாதவை**
கத்தரிக்காய், அவரைக்காய், பாகற்காய், வெண்டைக்காய்,கொத்தவரை,வெங்காயம், நூல்கோல், காலிபிளவர், வெள்ளைப்பூசணி, முட்டைகோஸ், முருங்கைக்காய், வாழைத்தண்டு, புடலங்காய், பலாக்காய், பீன்ஸ், கீரை வகைகள், பயறு வகைகள்,	வாழைக்காய்,உருளைக்கிழங்கு, காரட், பீட்ரூட் ,சேப்பங்கிழங்கு சர்க்கரைப்பூசணி கிழங்கு வகைகள், இளநீர், சிவப்பு முள்ளங்கி, நிலக்கடலை, முந்திரி

பழங்கள்

சாப்பிடக் கூடியவை	**சாப்பிடக் கூடாதவை**
சிறிய ஆப்பிள்1 பப்பாளிப் பழம் 1 துண்டு சிறிய ஆரஞ்சு வெள்ளரிப் பழம் 1 துண்டு, பேரிக்காய் சிறியது 1/2 துண்டு, கொய்யாப்பழம் சிறியது 1	பேரிச்சம் பழம் பலாப்பழம், உலர்ந்த பழ வகைகள், வாழைப்பழம், டின்னில் அடைக்கப்பட்ட பழ வகைகள், பெரிய ஆப்பிள், சப்போட்டா, மாம்பழம், பெரிய கொய்யாப்பழம்

பானங்கள்

சாப்பிடக் கூடியவை	**சாப்பிடக் கூடாதவை**
சர்க்கரை இல்லாத காபி டீ எலுமிச்சை ஜூஸ், சூப், சோடா, தக்காளி ஜூஸ், இளநீர் (சர்க்கரை கட்டுப்பாட்டில் இருந்தால்)	சர்பத் வகைகள் சர்க்கரை வகைகள், மது வகைகள், ஓவல்டின், ஹார்லிக்ஸ், போர்ன்விட்டா,

அசைவ உணவு வகைகள்

சாப்பிடக் கூடியவை	**சாப்பிடக் கூடாதவை**
முட்டை வெள்ளைக்கரு	முட்டையில் மஞ்சள் கரு, கருவாடு, மீன், ஈரல், மூளை, நெஞ்சுக்கறி, ஆட்டுக்கறி, கோழிக்கறி

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FORM VIII DIETARY ADVICE FORM

Vegetables

Eat	Avoid
Brinjal,Broad beans,Bitterguord,Lady's finger, Cluster beans, Onion, Turnip,Cauliflower, White pumpkin, Cabbage, Drumstick,Spadix of the Plaintain ,Cucumber,Beans, Green vegetables, Pulses	Unripe plantain, Potato, Carrot, Beetroot, Colachasia, Sweet pumpkin,Tubers, Tender coconut, Radish, Ground nut, Cashewnut

Fruits

Eat	Avoid
Small Apple 1, Papaya 1piece ,Small Orange, Muskmelon 1 piece, small Pear (1/2) piece, Guava small piece 1	Dates,Jackfruit,Dried fruits, Banana, Tinned fruits, Apple, Sapota, Mango,Guava

Drinks

Eat	Avoid
Coffee, Tea without sugar,Soda,Lime juice, Soup, Tomato juice, Tender coconut(If sugar level is controlled)	Sugar items, Honey, Oval,Horlicks,Bournvita

Non vegetarian foods

Eat	Avoid
Egg yolk,	Dry fish, Meat,Chicken